PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF THE RECORDING OF A CHANGE

(PCT Rule 92bis.1 and Administrative Instructions, Section 422)

To:

WOODCRAFT, David, Charles
Brookes Batchellor
102-108 Clerkenwell Road
London EC1M 5SA
ROYAUME-UNI

Date of mailing (day/month/year)
03 juillet 2001 (03.07.01)

Applicant's or agent's file reference
DCW/AKW

IMPORTANT NOTIFICATION

International application No.
PCT/GB00/02133

International filing date (day/month/year)
02 juin 2000 (02.06.00)

1. The following indications appeared on record concerning:

[ ] the applicant [ ] the inventor [X] the agent [ ] the common representative

Name and Address
WOODCRAFT, David, Charles
Brookes & Martin
High Holborn House
52/54 High Holborn
London WC1V 6SE
United Kingdom

State of Nationality:
State of Residence:
Telephone No.: 020 7242 9631
Facsimile No.: 020 7831 0586
Teleprinter No.:

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

[ ] the person [ ] the name [X] the address [ ] the nationality [ ] the residence

Name and Address
WOODCRAFT, David, Charles
Brookes Batchellor
102-108 Clerkenwell Road
London EC1M 5SA
United Kingdom

State of Nationality:
State of Residence:
Telephone No.: 020-7253-1563
Facsimile No.: 020-7253-1214
Teleprinter No.:

3. Further observations, if necessary:

4. A copy of this notification has been sent to:

[X] the receiving Office
[ ] the International Searching Authority
[X] the International Preliminary Examining Authority
[ ] the designated Offices concerned
[X] the elected Offices concerned
[ ] other:

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland
Facsimile No.: (41-22) 740.14.35

Authorized officer
Maria Victoria CORTIELLO
Telephone No.: (41-22) 338.83.38

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

Commissioner
US Department of Commerce
United States Patent and Trademark
Office, PCT
2011 South Clark Place Room
CP2/5C24
Arlington, VA 22202
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 15 January 2001 (15.01.01)	
International application No. PCT/GB00/02133	**Applicant's or agent's file reference** DCW/AKW
International filing date (day/month/year) 02 June 2000 (02.06.00)	**Priority date** (day/month/year) 04 June 1999 (04.06.99)
Applicant WILLIAMS, Jill, Ann et al	

1. The designated Office is hereby notified of its election made:

[X] in the demand filed with the International Preliminary Examining Authority on:

03 November 2000 (03.11.00)

[ ] in a notice effecting later election filed with the International Bureau on:

2. The election [X] was

[ ] was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO **34, chemin des Colombettes** **1211 Geneva 20, Switzerland**	Authorized officer Jean-Marc Vivet
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

Form PCT/IB/331 (July 1992)

GB0002133

PCT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION RELATING TO PRIORITY CLAIM

(PCT Rules 26bis.1 and 26bis.2 and Administrative Instructions, Sections 402 and 409)

To:

WOODCRAFT, David, Charles
Brookes & Martin
High Holborn House
52/54 High Holborn
London WC1V 6SE
ROYAUME-UNI

Date of mailing (day/month/year) 17 July 2000 (17.07.00)	
Applicant's or agent's file reference DCW/AKW	**IMPORTANT NOTIFICATION**
International application No. PCT/GB00/02133	International filing date (day/month/year) 02 June 2000 (02.06.00)
Applicant DENFOTEX LTD. et al	

The applicant is hereby **notified** of the following in respect of the priority claim(s) made in the international application.

1. [X] **Correction of priority claim.** In accordance with the applicant's notice received on: 22 June 2000 (22.06.00), the following priority claim has been corrected to read as follows:

GB 14 January 2000 (14.01.00) 0000882.1

- [ ] even though the indication of the number of the earlier application is missing.
- [ ] even though the following indication in the priority claim is not the same as the corresponding indication appearing in the priority document:

2. [ ] **Addition of priority claim.** In accordance with the applicant's notice received on: , the following priority claim has been added:

- [ ] even though the indication of the number of the earlier application is missing.
- [ ] even though the following indication in the priority claim is not the same as the corresponding indication appearing in the priority document:

3. [ ] As a **result of the correction and/or addition** of (a) priority claim(s) under items 1 and/or 2, the (earliest) priority date is:

4. [ ] **Priority claim considered not to have been made.**
   - [ ] The applicant failed to respond to the Invitation under Rule 26bis.2(a) (Form PCT/IB/316) within the prescribed time limit.
   - [ ] The applicant's notice was received after the expiration of the prescribed time limit under Rule 26bis.1(a).
   - [ ] The applicant's notice failed to correct the priority claim so as to comply with the requirements of Rule 4.10.

   The applicant may, before the technical preparations for international publication have been completed and subject to the payment of a fee, request the International Bureau to publish, together with the international application, information concerning the priority claim. See Rule 26bis.2(c) and the PCT Applicant's Guide, Volume I, Annex B2(IB).

5. [ ] In case where **multiple priorities** have been claimed, the above item(s) relate to the following priority claim(s):

6. A copy of this notification has been sent to the receiving Office and
   - [X] to the International Searching Authority (where the international search report has not yet been issued).
   - [X] the designated Offices (which have already been notified of the receipt of the record copy).

The International Bureau of WIPO **34, chemin des Colombettes** **1211 Geneva 20, Switzerland**	Authorized officer Lazar Joseph Panakal
Facsimile No. (41-22) 740.14.35	Telephone No. (41-22) 338.83.38

Form PCT/IB/318 (July 1998)

003412619

PCT

REQUEST

The undersigned requests that the present international application be processed according to the Patent Cooperation Treaty.

For receiving Office use only

International Application No.

International Filing Date

Name of receiving Office and "PCT International Application"

Applicant's or agent's file reference *(if desired) (12 characters maximum)* DCW/AKW

Box No. I TITLE OF INVENTION

METHOD AND APPARATUS FOR FILLING A DENTAL ROOT CANAL

Box No. II APPLICANT

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

DENFOTEX LTD.
WYNDHAM
HOPHURST HILL
CRAWLEY DOWN
WEST SUSSEX RH10 4LP
GB

☐ This person is also inventor.

Telephone No.

Facsimile No.

Teleprinter No.

State *(that is, country)* of nationality: GB

State *(that is, country)* of residence: GB

This person is applicant for the purposes of: ☐ all designated States ☒ all designated States except the United States of America ☐ the United States of America only ☐ the States indicated in the Supplemental Box

Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

~~HAMILTON, David Corbett~~
17 The Ness
Dollar
Falkirk FK14 7EB
GB

This person is:

☐ applicant only

☒ applicant and inventor

☐ inventor only *(If this check-box is marked, do not fill in below.)*

State *(that is, country)* of nationality: GB

State *(that is, country)* of residence: GB

This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☒ the United States of America only ☐ the States indicated in the Supplemental Box

☒ Further applicants and/or (further) inventors are indicated on a continuation sheet.

Box No. IV AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRESPONDENCE

The person identified below is hereby/has been appointed to act on behalf of the applicant(s) before the competent International Authorities as: ☒ agent ☐ common representative

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)*

WOODCRAFT, David Charles
BROOKES & MARTIN
High Holborn House
52/54 High Holborn
London WC1V 6SE
GB

Telephone No.
020 7242 9631

Facsimile No.
020 7831 0586

Teleprinter No.

☐ **Address for correspondence:** Mark this check-box where no agent or common representative is/has been appointed and the space above is used instead to indicate a special address to which correspondence should be sent.

Continuation of Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)

If none of the following sub-boxes is used, this sheet should not be included in the request.

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

~~COLLIS, Michael John~~
Bogleshowe
Hartree, Biggar
Lanarkshire ML12 6JJ
GB

This person is:
- ☐ applicant only
- ☒ applicant and inventor
- ☐ inventor only *(If this check-box is marked, do not fill in below.)*

State *(that is, country)* of nationality: GB

State *(that is, country)* of residence: GB

This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☒ the United States of America only ☐ the States indicated in the Supplemental Box

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

WILLIAMS, Jill Ann
32 The Gower
Thorpe TW20 8UD
GB

This person is:
- ☐ applicant only
- ☒ applicant and inventor
- ☐ inventor only *(If this check-box is marked, do not fill in below.)*

State *(that is, country)* of nationality: GB

State *(that is, country)* of residence: GB

This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☒ the United States of America only ☐ the States indicated in the Supplemental Box

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

CLEMENTS, David John
Wyndham
Hophurst Hill
Crawley Down
West Sussex RH10 4LP
GB

This person is:
- ☐ applicant only
- ☒ applicant and inventor
- ☐ inventor only *(If this check-box is marked, do not fill in below.)*

State *(that is, country)* of nationality: GB

State *(that is, country)* of residence: GB

This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☒ the United States of America only ☐ the States indicated in the Supplemental Box

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

PEARSON, Gavin John
Flintstones
Chapel Lane
Ashampstead, Nr. Reading
Berks RG8 8RU
GB

This person is:
- ☐ applicant only
- ☒ applicant and inventor
- ☐ inventor only *(If this check-box is marked, do not fill in below.)*

State *(that is, country)* of nationality: GB

State *(that is, country)* of residence: GB

This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☒ the United States of America only ☐ the States indicated in the Supplemental Box

☒ Further applicants and/or (further) inventors are indicated on another continuation sheet.

Continuation of Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)

If none of the following sub-boxes is used, this sheet should not be included in the request.

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

WILSON, Michael
c/o Eastman Dental Institute for Oral Health Care Sciences
University of London
256 Gray's Inn Road
London WC1X 8LD
GB

This person is:
- ☐ applicant only
- ☒ applicant and inventor
- ☐ inventor only *(If this check-box is marked, do not fill in below.)*

State *(that is, country)* of nationality: GB

State *(that is, country)* of residence: GB

This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☒ the United States of America only ☐ the States indicated in the Supplemental Box

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

This person is:
- ☐ applicant only
- ☐ applicant and inventor
- ☐ inventor only *(If this check-box is marked, do not fill in below.)*

State *(that is, country)* of nationality:

State *(that is, country)* of residence:

This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☐ the United States of America only ☐ the States indicated in the Supplemental Box

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

This person is:
- ☐ applicant only
- ☐ applicant and inventor
- ☐ inventor only *(If this check-box is marked, do not fill in below.)*

State *(that is, country)* of nationality:

State *(that is, country)* of residence:

This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☐ the United States of America only ☐ the States indicated in the Supplemental Box

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

This person is:
- ☐ applicant only
- ☐ applicant and inventor
- ☐ inventor only *(If this check-box is marked, do not fill in below.)*

State *(that is, country)* of nationality:

State *(that is, country)* of residence:

This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☐ the United States of America only ☐ the States indicated in the Supplemental Box

☐ Further applicants and/or (further) inventors are indicated on another continuation sheet.

Box No.V DESIGNATION OF STATES

The following designations are hereby made under Rule 4.9(a) *(mark the applicable check-boxes; at least one must be marked)*:

Regional Patent

☒ **AP** **ARIPO Patent:** **GH** Ghana, **GM** Gambia, **KE** Kenya, **LS** Lesotho, **MW** Malawi, **SD** Sudan, **SL** Sierra Leone, **SZ** Swaziland, **TZ** United Republic of Tanzania, **UG** Uganda, **ZW** Zimbabwe, and any other State which is a Contracting State of the Harare Protocol and of the PCT

☒ **EA** **Eurasian Patent:** **AM** Armenia, **AZ** Azerbaijan, **BY** Belarus, **KG** Kyrgyzstan, **KZ** Kazakhstan, **MD** Republic of Moldova, **RU** Russian Federation, **TJ** Tajikistan, **TM** Turkmenistan, and any other State which is a Contracting State of the Eurasian Patent Convention and of the PCT

☒ **EP** **European Patent:** **AT** Austria, **BE** Belgium, **CH and LI** Switzerland and Liechtenstein, **CY** Cyprus, **DE** Germany, **DK** Denmark, **ES** Spain, **FI** Finland, **FR** France, **GB** United Kingdom, **GR** Greece, **IE** Ireland, **IT** Italy, **LU** Luxembourg, **MC** Monaco, **NL** Netherlands, **PT** Portugal, **SE** Sweden, and any other State which is a Contracting State of the European Patent Convention and of the PCT

☒ **OA** **OAPI Patent:** **BF** Burkina Faso, **BJ** Benin, **CF** Central African Republic, **CG** Congo, **CI** Côte d'Ivoire, **CM** Cameroon, **GA** Gabon, **GN** Guinea, **GW** Guinea-Bissau, **ML** Mali, **MR** Mauritania, **NE** Niger, **SN** Senegal, **TD** Chad, **TG** Togo, and any other State which is a member State of OAPI and a Contracting State of the PCT *(if other kind of protection or treatment desired, specify on dotted line)* .....

National Patent *(if other kind of protection or treatment desired, specify on dotted line)*:

☒ **AE** United Arab Emirates
☒ **AL** Albania .....
☒ **AM** Armenia .....
☒ **AT** Austria .....
☒ **AU** Australia .....
☒ **AZ** Azerbaijan
☒ **BA** Bosnia and Herzegovina .....
☒ **BB** Barbados
☒ **BG** Bulgaria .....
☒ **BR** Brazil .....
☒ **BY** Belarus .....
☒ **CA** Canada
☒ **CH and LI** Switzerland and Liechtenstein
☒ **CN** China .....
☒ **CR** Costa Rica .....
☒ **CU** Cuba .....
☒ **CZ** Czech Republic .....
☒ **DE** Germany .....
☒ **DK** Denmark .....
☒ **DM** Dominica
☒ **EE** Estonia .....
☒ **ES** Spain .....
☒ **FI** Finland .....
☒ **GB** United Kingdom
☒ **GD** Grenada
☒ **GE** Georgia .....
☒ **GH** Ghana .....
☒ **GM** Gambia
☒ **HR** Croatia .....
☒ **HU** Hungary .....
☒ **ID** Indonesia
☒ **IL** Israel .....
☒ **IN** India .....
☒ **IS** Iceland
☒ **JP** Japan .....
☒ **KE** Kenya .....
☒ **KG** Kyrgyzstan .....
☒ **KP** Democratic People's Republic of Korea .....
☒ **KR** Republic of Korea .....
☒ **KZ** Kazakhstan .....
☒ **LC** Saint Lucia
☒ **LK** Sri Lanka
☒ **LR** Liberia
☒ **LS** Lesotho .....
☒ **LT** Lithuania
☒ **LU** Luxembourg
☒ **LV** Latvia
☒ **MA** Morocco .....
☒ **MD** Republic of Moldova .....
☒ **MG** Madagascar .....
☒ **MK** The former Yugoslav Republic of Macedonia .....
☒ **MN** Mongolia
☒ **MW** Malawi .....
☒ **MX** Mexico .....
☒ **NO** Norway
☒ **NZ** New Zealand .....
☒ **PL** Poland .....
☒ **PT** Portugal .....
☒ **RO** Romania
☒ **RU** Russian Federation .....
☒ **SD** Sudan
☒ **SE** Sweden
☒ **SG** Singapore
☒ **SI** Slovenia .....
☒ **SK** Slovakia .....
☒ **SL** Sierra Leone .....
☒ **TJ** Tajikistan .....
☒ **TM** Turkmenistan .....
☒ **TR** Turkey .....
☒ **TT** Trinidad and Tobago .....
☒ **TZ** United Republic of Tanzania
☒ **UA** Ukraine .....
☒ **UG** Uganda .....
☒ **US** United States of America .....
☒ **UZ** Uzbekistan .....
☒ **VN** Viet Nam .....
☒ **YU** Yugoslavia .....
☒ **ZA** South Africa .....
☒ **ZW** Zimbabwe .....

Check-boxes reserved for designating States which have become party to the PCT after issuance of this sheet:

☐ .....
☐ .....

Precautionary Designation Statement: In addition to the designations made above, the applicant also makes under Rule 4.9(b) all other designations which would be permitted under the PCT except any designation(s) indicated in the Supplemental Box as being excluded from the scope of this statement. The applicant declares that those additional designations are subject to confirmation and that any designation which is not confirmed before the expiration of 15 months from the priority date is to be regarded as withdrawn by the applicant at the expiration of that time limit. *(Confirmation (including fees) must reach the receiving Office within the 15-month time limit.)*

Box No. VI PRIORITY CLAIM ☐ Further priority claims are indicated in the Supplemental Box.

Filing date of earlier application (day/month/year)	Number of earlier application	Where earlier application is: national application: country	regional application:* regional Office	international application: receiving Office
item (1) 04-06-99	9913100.5	GB		
item (2) 14-01-00	0000884.7	GB		
item (3) 14-01-00	0000886.1	GB		

☒ The receiving Office is requested to prepare and transmit to the International Bureau a certified copy of the earlier application(s) *(only if the earlier application was filed with the Office which for the purposes of the present international application is the receiving Office)* identified above as item(s): _____

** Where the earlier application is an ARIPO application, it is mandatory to indicate in the Supplemental Box at least one country party to the Paris Convention for the Protection of Industrial Property for which that earlier application was filed (Rule 4.10(b)(ii)). See Supplemental Box.*

Box No. VII INTERNATIONAL SEARCHING AUTHORITY

Choice of International Searching Authority (ISA) *(if two or more International Searching Authorities are competent to carry out the international search, indicate the Authority chosen; the two-letter code may be used)* :

ISA /

Request to use results of earlier search; reference to that search *(if an earlier search has been carried out by or requested from the International Searching Authority):*

Date *(day/month/year)* Number Country *(or regional Office)*

Box No. VIII CHECK LIST; LANGUAGE OF FILING

This international application contains the following **number of sheets**:

request	: 5
description (excluding sequence listing part)	: 29
claims	: 4
abstract	: 0
drawings	: 4
sequence listing part of description	: 0
Total number of sheets	: 42

This international application is **accompanied** by the item(s) marked below:

1. ☐ fee calculation sheet
2. ☐ separate signed power of attorney
3. ☐ copy of general power of attorney; reference number, if any:
4. ☐ statement explaining lack of signature
5. ☐ priority document(s) identified in Box No. VI as item(s):
6. ☐ translation of international application into (language):
7. ☐ separate indications concerning deposited microorganism or other biological material
8. ☐ nucleotide and/or amino acid sequence listing in computer readable form
9. ☐ other *(specify)*:

Figure of the drawings which should accompany the abstract: 1

Language of filing of the international application: English

Box No. IX SIGNATURE OF APPLICANT OR AGENT

Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from reading the request).

David Charles WOODCRAFT
02.06.00

For receiving Office use only

1. Date of actual receipt of the purported international application:
2. Drawings: ☐ received: ☐ not received:
3. Corrected date of actual receipt due to later but timely received papers or drawings completing the purported international application:
4. Date of timely receipt of the required corrections under PCT Article 11(2):
5. International Searching Authority (if two or more are competent): ISA /
6. ☐ Transmittal of search copy delayed until search fee is paid.

For International Bureau use only

Date of receipt of the record copy by the International Bureau:

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
14 December 2000 (14.12.2000)

PCT

(10) International Publication Number
WO 00/74587 A1

(51) International Patent Classification[7]: A61C 5/00

(21) International Application Number: PCT/GB00/02133

(22) International Filing Date: 2 June 2000 (02.06.2000)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

9913100.5	4 June 1999 (04.06.1999)	GB
0000882.1	14 January 2000 (14.01.2000)	GB
0000886.1	14 January 2000 (14.01.2000)	GB

(71) Applicant *(for all designated States except US)*: **DENFOTEX LTD.** [GB/GB]; Wyndham, Hophurst Hill, Crawley Down, West Sussex RH10 4LP (GB).

(72) Inventors; and

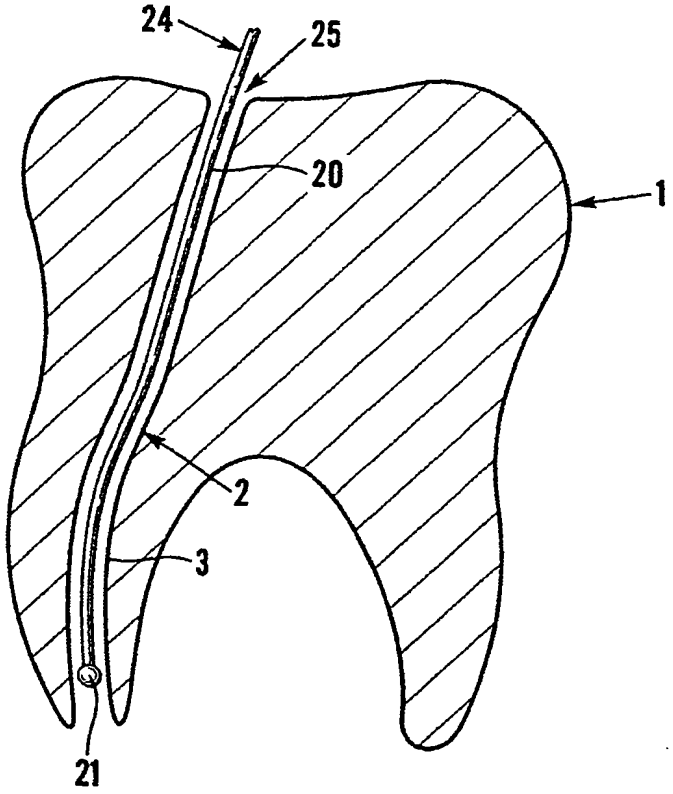
(75) Inventors/Applicants *(for US only)*: **WILLIAMS, Jill, Ann** [GB/GB]; 32 The Gower, Thorpe TW20 8UD (GB). **CLEMENTS, David, John** [GB/GB]; Wyndham, Hophurst Hill, Crawley Down, West Sussex RH10 4LP (GB). **PEARSON, Gavin, John** [GB/GB]; Flintstones, Chapel Lane, Ashampstead, Nr. Reading, Berks RG8 8RU (GB). **WILSON, Michael** [GB/GB]; Eastman Dental Institute for Oral Health Care Sciences, University of London, 256 Gray's Inn Road, London WC1X 8LD (GB).

(74) Agent: **WOODCRAFT, David, Charles**; Brookes & Martin, High Holborn House, 52/54 High Holborn, London WC1V 6SE (GB).

(81) Designated States *(national)*: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU,

[Continued on next page]

(54) Title: METHOD AND APPARATUS FOR FILLING A DENTAL ROOT CANAL



(57) Abstract: A dental root canal is treated by a flowable photosensitiser and thereafter filled by obturating means for sealing the canal. During this treatment an optical fibre is introduced into the root canal, said optical fibre being connectable proximally with means for generating laser light.

WO 00/74587 A1

LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

(84) **Designated States** *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:
— *With international search report.*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

METHOD AND APPARATUS FOR FILLING A DENTAL ROOT CANAL

This invention relates to the treatment of a dental root canal including the obturation of the canal.

Background of the Invention

There are a number of situations in which treatment of root canals in teeth is indicated. The tissue lying within the tooth structure, the dental pulp, may become diseased as a result of dental caries or the cells and tissue may be traumatised or atrophy. As a result of this, the pulp tissue may die and/or become infected. This leads to death of the pulp. While it has been common practice to extract the tooth, use of the tooth can be preserved by the removal of the diseased tissue and sealing the cleaned and sterilised canal. The operation of mechanically removing the diseased pulp is technically difficult and require the accessing of the canal and removing infected tissue, which may be at or near the apex of the root of the tooth. The treatment becomes more complex as the anatomy of the root canal becomes more complex and the canals themselves become narrower.

Conventional endodontic treatment involves first gaining access to the pulp chamber by removing the overlying enamel and dentine. Once the pulp chamber is exposed, the entrances to the root canals are then located and enlarged. The length of the root canal is calculated from a diagnostic radiograph or by means of an apex locator and the canal is instrumented using files and/or reamers of increasing size. These instruments are designed to remove the internal surface of the root canal by rasping and cutting the dentine walls. The dentine walls have small holes where the dentine forming cell processes track into the dentine. These holes are sites where

bacteria can settle and proliferate. It is these areas which are reduced by mechanical debriding of the internal surface of the root canal. To achieve this, the reamers and files are used to produce a root canal that, near the apex, is matched in size to the obturating device. The internal diameter of the canal is enlarged so that the cavities in the root wall are reduced in size and the canal is mechanically cleaned.

Medicaments may be used to chemically kill the bacteria; these are usually disinfectants and anti-bacterials such as hypochlorite solution or antibiotic pastes. These may be introduced into the root canal after initial mechanical debridement. These medicaments and mechanical methods of removal of tissue are designed to produce a root canal which is free of bacteria and other contaminants. Conventional procedures are time consuming and difficult to carry out since they require careful and extensive mechanical debridement of the canal walls and use of copious volumes of irrigants such as aqueous sodium hypochlorite to flush out the canal. The more posterior the tooth situation within the mouth the greater the risk of failure to achieve the objectives, since the root canals morphology becomes more convoluted and adequate access becomes more difficult to achieve.

Summary of the Invention

An important objective of the present invention is to simplify the treatment of dental root canals and to provide a treatment system which enables the dentist to be more confident that remnants of decay and bacterial contamination within the canal have been removed, prior to obturation of the canal to seal it.

Another object is to reduce the time normally required to prepare a root canal for obturation and also preparing the canal for alternative systems of obturating the canal which can be co-ordinated with the preparation of the canal.

According to one aspect of the invention there is provided a method of treating a dental root canal which comprises the steps of:-

(a) gaining access to the root canal;

(b) introducing a flowable photosensitiser into the root canal;

(c) activating the photosensitiser by exposing the walls of the root canal to laser light via an optical fibre within the root canal to kill bacteria within the root canal; and

(d) obturating the root canal.

As mentioned above, the root canal is first opened up and necrotic material removed by filing or reaming. One convenient method of cleaning out the root canal is by using endodontic instruments to produce a fluted, tapered tunnel. Normally, a series of instruments are used of similar length and the diameters at the tip increase sequentially. These instruments may be used both manually or, conveniently, may be fitted to a conventional rotary dental handpiece. During and after the canal shaping step, debris loosened by the mechanical debriding of the interior and walls of the canal is removed by irrigation and organic debris dissolved. Traditionally, aqueous sodium hypochlorite solution is used, e.g. at a concentration of 2~3%. These are used in copious volumes during the debriding procedure to remove solid debris or kill bacteria (Chow et al, 1983, J. Endodont. 9,475).

In the method of the present invention, sodium hypochlorite may be used for initially cleaning and flushing away loosened debris. However, an aqueous solution of the photosensitiser may alternatively be used in this step, or at least after the initial debris has been removed and the hypochlorite solution flushed away.

The next step is to introduce the photosensitiser dye into the root canal. Preferably, the photosensitiser is a toluidine blue dye which is employed in an aqueous solution, although other photosensitisers may be used as mentioned in EP 0637976. On contact with the bacteria, the dye or other photosensitiser conjugates with the bacteria and once photosensititation has occurred, the site is irradiated with light of a specific wavelength which is strongly absorbed by the photosensitiser. The wavelength of light is specific to the absorption of each photosensitiser. The activation of the dye leads to singlet oxygen release and results in death of the bacteria. It is important that the light is guided closely to areas which may be contaminated with bacteria. This is best done by introducing a light guide or optical fibre into the root canal. In order to ensure that the light is directed onto the walls of the root canal, the fibre tip should be appropriately shaped. The optic fibre may have a spherical or cylindrical surface in the region of the distal end. The production of this type of tip or emitter is described in US Patent No. 5,073,402. In essence, the tip is preferably formed by contacting the distal end of the optic fibre with a light-curable composition, which in its cured state is transparent or translucent, while passing coherent light through the fibre at a wavelength causing curing of the composition. Suitable light-curable compositions include acrylate and methacrylate monomers, including epoxy and urethane acrylates and methacrylates. Such compositions may

contain photochemical initiators and free radical generating additives such as α-diketones (camphoroquinone), benzoyl peroxides and dimethyl-p-toluidine. Alternatively the tips may be constructed from light polymerisable epoxy resins as described in PCT/US98/04458, "Ternary photoinitiator system for curing Epoxy/polyol compositions" and US Patent 6,043,295, "Ternary photoinitiator system for curing epoxy resins". Further photopolymerisable compositions that contain epoxides include US Patent 4, 256, 868, Smith, US Patent 4,835,193, Hayase, US Patent 5,545,676, Palazzotto et al. and WO 95/14716, Neckers et al. It may also be desirable to include a minor amount of a dispersed pigment in the tip, e.g. up to about 1~2% by weight of a white pigment, such as TiO_2. This has a scattering effect of the light transmitted by the fibre and ensures that the walls of the canal are uniformly illuminated. A generally isotropic tip can be formed by immersing the optic fibre tip in a bath of a light-curable composition, e.g. as described in US Patent No. 5,073,402. The shape of the tip may be predetermined, e.g. a cylindrical tip may be formed by introducing the fibre tip into a mould, such as a tube, containing the polymerisable composition. By selecting a polytetrafluoroethylene (PTFE) or silicone to form the mould, it can be readily stripped away after the light-curable resin has been polymerised. A tubular mould can be used to produce a cylindrical tip. A spherical tip can be produced by the technique described in the above US Patent. The optical fibre has a core, usually of glass, and a cladding which helps to enhance its strength and flexibility. Suitable claddings are plastics material such as polyamides and methacrylates. Prior to forming the tip, the end of the fibre is treated to strip cladding from the end of the fibre. A flame or concentrated acid can be used

for this purpose. The stripped and cleaned end is then immersed in a bath of light-polymerisable liquid resin composition and light passed through the fibre to form a pear-shaped droplet of "soft-cured" resin. The tip is then removed from the bath and the droplet hardened by passing light down the fibre for a further period, preferably at higher intensity. Cladding is removed from the tip so that the droplet of resin adheres both to the core and to the cladding. During the hardening stage, the droplet of soft-cured resin is maintained in a no-oxygen containing atmosphere, e.g., by immersing it in an inert gas or liquid, e.g., paraffin oil.

After the root canal has been treated with the photosensitiser and irradiated with light, the root canal is dried, e.g. by aspiration and using absorbent points. The canal is then obturated using a suitable system to seal the canal. This may involve the use of conventional sealing system such as shaped gutta percha, silver or titanium points cemented with an endodontic sealer. Examples of these include zinc oxide/ eugenol and calcium hydroxide based cements and also epoxy resins. Conventional obturation systems may be used such as those employing gutta percha are generally convenient. One suitable system involves introducing gutta percha in heated, softened form on a rod-like carrier into the canal. This procedure is described in European Patent Application No. 0337024. A similar procedure is described in US Patent No. 5149268.

Alternatively, the canal is obturated with a light-curable filling composition. The light curable composition may be cured by irradiation by light of a wavelength specific to activate the in situ system, introduced through an optical fibre positioned within the root canal. The optical fibre is generally provided with a distal tip for

spreading the light substantially uniformly, and may be the same optical fibre that is used to guide light into the canal to activate the photosensitiser. However, it may be necessary to use light of a different wavelength for curing the sealant than for activating the photosensitiser. After the filling material has been cured, the optical fibre may remain entombed in the root canal as part of the obturation.

The invention also includes a kit of parts for treating a dental root canal which comprises:-

(a) a flowable photosensitiser;

(b) an optical fibre having a distal portion for emitting light and adapted for introduction into a root canal so that the tip is capable of reaching the apical region of the root canal, said optical fibre being connectable proximally with a means for generating light; and

(c) obturating means for sealing the canal.

In one form of the invention, the obturating means is a flowable, light curable filling composition.

It will be appreciated therefore that in one aspect the invention makes use of a combination of a photosensitive substance and a light source operating at the appropriate wavelength to activate the photosensitiser. A further aspect of the invention is the delivery mechanism, which permits the delivery of the photosensitiser either at or near the apex of the root canal to ensure that the photosensitiser will contact the debris and bacteria. A related aspect of the invention is the provision of a specially shaped spherical or cylindrical tip to an optical fibre which permits application of light of appropriate wavelength to the region of the apex of a tooth. A

still further aspect is the provision of a specially shaped optical tip to provide uniform light near the apex of the tooth. A further element is the provision of a novel sealing or filling material, which will prevent re-infection of the canal from either the access cavity or via the apical foramen. The sealing or filling material may be delivered via the novel delivery system.

As mentioned above, the pulp chamber and coronal region of the root canal is accessed in the normal way using a high speed dental drill. Alternatively, a laser may be used to expose the pulpal chamber and the entrance to the root canal. After initial estimation of canal length which may be carried out by radiography or use of electro optical detection devices, the canal opening may be increased by reaming the canal. The canal may then be irrigated with a known irrigant such as with aqueous hypochlorite or more preferably with the photosensitiser. This may be achieved using a fine tipped syringe or, alternatively, with a specialised dispensing accessory as described below. Turbulent flow may be induced when injecting the photosensitiser into the canal as described in Gooden, 1976, 2: 2571, Chow J. Endodont 1983 9.47. Effective irrigation is achieved by preparing an inwardly tapered canal to ensure the irrigants reach to the apex. This may be facilitated by the use of appropriate instruments.

After introducing the photosensitising agent into the root canal in the tooth, the agent is activated using light delivered by an optical fibre from the specific light source. The wavelength employed depends on the absorption spectra of the photosensitiser. Toluidine blue O is preferably employed as the photosensitiser and has an absorption maximum in the range of 630~660 nm. Semiconductor lasers,

gallium/arsenide and helium/neon lasers may be used. The laser light may be continuous or pulsed. It has been found to be important to spread the laser light within the canal rather than focus it on a small target area. One way of achieving this is to provide an optical fibre which terminates in a tip of specific shape; this may be an isotropic tip of spherical configuration.

Another method is to provide a distal portion having curved surfaces, such as cylindrical surfaces. The light-spreading portion may be larger than the diameter of the optical fibre or substantially the same size. The light spreading portion may be formed by removing the internally reflecting outer layer of the optical fibre over a portion of the probe or by providing an extended portion of the desired shape having no internal reflecting portion. Alternatively, the internal light reflecting coating may be omitted in the desired area when forming the coating. One method of forming such a tip is described in US Patent No. 5,073,402.

Essentially, the light-spreading distal tip may be conveniently formed by moulding or casting a curable light transmissive composition on the end of the optical fibre. A spherical tip may be formed by dipping the optical fibre into a polymerisable composition and curing the adherent droplet, while supporting the droplet in a non-miscible, inert liquid. Curing may be effected by passing light of the appropriate wavelengths for curing along the optical fibre. Suitable polymerisable compositions include light curable acrylate and methacrylate compositions, including those described below as suitable sealant materials. It may be desirable to include a light-scattering material, such as a dispersed pigment in an amount of up to 5 % by weight, within the polymerisable material to increase the uniformity of irradiation of

the root canal. However, the cured tip will be transparent or translucent to light of the wavelength selected for sensitising the dye.

Other shaped tips may be formed by moulding or casting the desired shape onto the end of the optical fibre.

The Photosensitiser

The photosensitiser or dye is used for the disinfection of the internal surface of the root canal by placing a liquid or gel containing the photosensitiser in contact with the debris and bacteria. The interior of the root canal is then irradiated with light of an appropriate wavelength that will be absorbed by the photosensitiser.

In preferred aspects of the invention, the photosensitiser and laser combination may be applied to:-

(a) disinfection or sterilisation of the root canal after initial access has been gained to the root canal of the infected tooth; or as an adjunct to conventional preparation prior to obturate of the canal;

(b) destruction of carious microbes on the internal root surface in order to prevent reinfection.

Photosensitising agents used in this invention are generally non toxic to the target microbes in the concentrations envisaged or to the surrounding tissue. However, there is no requirement that the photosensitiser should not be toxic to the microbes. Since the exposure times are short, it may be acceptable to use compounds which have some slight toxicity to the tissue.

It is preferred that the photosensitisers used will be capable of absorption in the red end of the visible spectrum or at longer wavelength, as these wavelengths will have greater penetrating powers in the dental tissue surrounding the canal.

The preferred photosensitisers are those effective against Gram Negative bacteria associated with endodontic lesions. Common types of bacteria found in root canal infections contain facultative anaerobes and strict anaerobes and are described in Lewes MAO, McFarlane TW and McGowan DAJ Medical Microbiology 21:101:1986. These include:-

Facultative Anaerobes including Streptococcus milleri and Actinomyces naeslundi. Strict Anaerobes including Bacteroides gingivalis, Bacteroides melaninigenicus, Bacteroides oralis, Peptococcus species and Peptostreptoccus species. The classification of these bacteroides type bacteria include Porphyromonas [gingivalis and endodontalis] and Prevotella [melaninogenica and intermedia]. The presence of these bacteria in an infected root canal or after inadequate cleaning will lead to infection and pain and discomfort. The function of the photosensitiser is to bind to the bacteria and to release singlet oxygen on interacting with the laser light. Of the available photosensitisers, the currently preferred is Toluidine blue O. Alternatively, aluminium disulphonated phthalocyanine chloride, methylene blue or azure blue chloride may be used. While the dye may be non specific, it can be made specific to the microbes within the root canal.

The Laser

The concentration of photoinitiator and laser power are matched to provide maximum penetration of tissue and kill rates.

The concentrations of dye range from 0.00001% to 2%. The currently preferred concentration is 0.0001 to 0.2%, especially 0.001 to 0.1%.

The preferred laser irradiation time of the photosensitiser is between 10 seconds and two minutes and the preferred exposure time is between 30 seconds and 90 seconds.

The laser power is preferably between 25 and 150 mW, the most preferred being about 80 mW. The laser power/exposure time combination may be varied to give a desired dose.

The photosensitiser solution concentration may be influenced by any extrinsic fluid and concentration may be increased to compensate for this.

In order to modify the surface of hard tissue and to enable the photosensitising agents to have maximum effect, potentiating agents may be used as adjuncts to the photosensitising solution. These may be used in conjunction with, prior to or subsequent to the photosensitising solution. These adjuncts include:-

- Acids to produce a solution pH of 4.5 or above
- Acids to penetrate and remove organic/inorganic debris
- Wetting agents such as HEMA (hydroxyethyl methacrylate) and glutaraldehyde
- Demineralising agents such as chelating agents of the type EDTA disodium.

Such materials may be citric acid, polyalkenoic and polyphosphonic acid, phosphoric acid, EDTA and HEMA or other such acids as are known for use in this technique. EDTA and citric acid have an adverse effect on the bacterial kill rate if

used simultaneously with the photosensitiser. Thus, in the case of these adjuncts, they should be employed prior to or after treatment with the photosensitiser and the treated area flushed with a wash liquid prior to treatment with the photosensitiser. Phosphoric acid, particularly when buffered to a pH of 4.5 or above appears not to adversely affect bacterial kill rates when used at the same time as the photosensitisation treatment.

It is important that these agents do not interfere with the photosensitising process, in particular the use of free radical and singlet oxygen scavenging materials should be avoided.

The photosensitiser may be delivered by a syringe or by a unit dose delivery device, which may include a thin flexible tube which may be perforated along the final part of its distal end, e.g. the last 15 mm of its length. The perforated tube, whose diameter is preferably a maximum of 0.1 mm, will be inserted up the canal without binding against the walls. This will normally be within the apical third of the canal (this being the third of the root canal closest to the root apex), and as close to the apex as achievable without binding on the walls. The dye is then injected, e.g. via a unit dose cartridge, through the tube permitting the dye to coat the whole length of the walls of the root canal. The unit dose syringe and tube will then be removed and the fibre connected to a suitable light source and inserted into the canal. The photosensitiser dye will be activated by the light source.

The filling or sealing material

A further aspect of the invention is that a fluid sealing agent may be syringed up through the delivery system previously described in connection with the

photosensitiser. This will coat the walls of the root canal and displace air from the canal as it fills the canal through a tube or syringe tip terminating in the region of the apex. The sealing agent may then be cured using a visible light source, via an optical fibre tipped with an isotropic tip.

These may be resins such as those described as dental adhesives in Patent Application Nos. PCT/GB92/02128; PCT/GB98/00072; US 5,172,763 and US 5,063,257, and other curable resin systems which are employed as dental adhesive and filling materials, e.g. those described in the following patents and applications:]

EP 0356868	WO 97/00065
GB 2107341	UK 1488403
US 5520725	US 4627097
US 1428165	US 4001483

The hermetic seal after bacterial killing is an integral part of the endodontic treatment technique since it is by these means that the bacterial re-infection is minimised. This may be achieved using existing dental materials.

The preferred materials may have a viscosity which may be varied to suit the application. Preferred viscosities are from 0.33 to 1340 centipoise. Where it is used as a dentine substitute, the viscosity is similar to that of water and has mechanical properties such as flexural strength after polymerisation in the range 80 to 170 Mpa. Shrinkage during polymerisation will be in the range of 0.5 to 4.5% by volume. The sealing agent is made of a blend of resins, which will provide a range of viscosities to suit the intended application.

These may be di-methacrylates or methacrylates as set out in the patents mentioned above. The preferred resin system is a mixture of urethane dimethacrylate (UDMA), bisphenol-A-glycidyl dimethacrylate (BisGMA) and tetrahydrofurfuryl methacrylate (THFMA), which contains THFMA in the range of 30~90% by weight of THFMA. These may be in various proportions, the preferred composition being THFMA 50%, UDMA 33% and BisGMA 17%.

The material may be polymerised chemically or by application of light of a particular wavelength. Sealant materials based on light curable acrylates or methacrylates are commonly cured with light having a wavelength of about 450-470nm.

Cold cure initiator systems which do not require the addition of external energy (heat or light) are materials such as benzoyl peroxide as an initiator and N,N-dimethyl-p-toluidine as an activator.

Preferred light activation systems are those including camphorquinone and an amine. Other activation systems may also be used.

The initiators should be present in an appropriate amount to provide an adequate level of conversion and adequate rate of conversion. They are usually present in amounts between 0.1% and 12% of the weight of the monomer mixture. Preferred values are between 0.5 and 5% by weight of the monomer mixture.

Various additives may optionally be included in the mixture such as antioxidants, stabilisers using UV inhibitors and polymerisation inhibitors, pigments and therapeutic agents such as antibiotics, corticosteroids and other medicinal agents such as metal ions.

Alternative materials such as sol-gel glasses may also be used as the sealing agents delivered in a similar manner to that described above. Other useful sealing materials include light-polymerisable epoxy resins as mentioned above and described in PCT/US98/04458 and US Patent 6,043,295.

The most preferred obturating materials comprise those which seal the canal by deformation under pressure. The root canal sealer which acts as a sealing agent between the canal wall and the obturating material is gutta percha. Its properties allow it to be compressed against the canal wall. The gutta percha points are matched in size to the shaped canal. The gutta percha can be laterally condensed, vertically condensed, heat or cold compacted. A range of additional techniques may be used including heat softening and adapting. Injection of warm gutta percha may also be used. The technique recommended by Tulsa Dental Co. under the name "Thermafil" might also be used to obturate the canal. Here the gutta percha is formed around a plastic pin. The gutta percha is heated and the pin and gutta percha inserted into the root canal. Pressure is applied with the plastic pin forcing the softened material into all the orifices in the canal walls.

A major advantage of the present invention is that the technique of applying laser light to the photosensitiser within the canal gives a much higher level of assurance to the dentist that residual infection has been eradicated. In part, this is because the photosensitiser is absorbed into the side passages leading from the main canal and that the laser light passes through a significant thickness of dentine.

The following is an experimental evaluation of the effectiveness of the PDT technique against organisms implicated in endodontal infections.

(i) Target Bacteria

A wide variety of bacteria have been implicated in endodontal infections. However, the current literature suggests that the most important species are the following:

Peptostreptococcus micros, Fusobacterium nucleatum, Prevotella intermedia, Streptococcus intermedium and Streptococcus mutans.

(ii) Experimental Procedures

The aim of this part of the work was to determine whether PDT is able to achieve substantial kills of the target organisms. The criteria for success would be the killing of all target organisms by low light doses in the presence of clinically-acceptable concentrations of toluidine blue O (TBO).

Two key experimental parameters were selected – TBO concentration and light energy dose. In order to investigate the effects of these parameters on bacterial killing, a quantitative assay established and employed in previous studies was used.

The basic experimental protocol consisted of the following. The target organisms were grown for 24 – 48 h (depending on the particular species) in fastidious anaerobe broth at 37°C in an anaerobic cabinet. 30µl aligquots of a suspension of each organism in 0.85 % (w/v) saline were then transferred to wells of a 96-well, round-bottomed micro-titre plate and an equal volume of a saline (0.85 % w/v) solution of the TBO added to each well. Duplicate wells were exposed to light from the laser diode (following immersion of the tip of the optical fibre in the suspension) for the requisite period of time. Control wells containing the microbial suspension plus 0.85 % (w/v) saline in place of the TBO were treated in an identical

manner to determine the effect of laser light along at a wave length of 640 nm on bacterial viability. A further four wells, identical to those described above, were prepared and kept in the dark. Hence the effect on bacterial viability of the TBO alone was ascertained. After irradiation of appropriate wells, serial dilutions of the contents of each well were prepared in sterile nutrient broth and 50 µl aliquots spread over the surfaces of blood agar plates. After anaerobic incubation of the plates for up to 7 days at 37°C the resulting colonies were counted.

Using the method described above the following results were obtained on anaerobic organisms.

TABLE 1

Exposure Time 30sec Laser Power 80mW

Dye Concentration [µg/mL	Organism	Initial cfu	% Bacterial kill	Mean
20	Streptococcus intermedius	1.46E8 4.90E10	99.914 99.286	99.6
20	Peptostreptococcus micros	3.23E8 1.94E9	99.901 98.865	99.38
20	Fusobacterium nucleatum	6.98E6	99.959	

TABLE 2

Exposure Time 60sec Laser Power 80mW

Dye Concentration [µg/mL	Organism	Initial cfu	% Bacterial kill	Mean
10	Streptococcus intermedius	2.85E8 3.56E8	99.9997 99.9958	99.998
20	Peptostreptococcus micros	2.45E9 2.49E8	99.999 99.996	99.998
20	Fusobacterium nucleatum	1.32E7 1.57E7	99.934 99.841	99.998

Lethal photosensitisation of Streptococcus mutans in a saline suspension.

Experiments have been carried out using a range of concentrations of Toluidene blue O (TBO). These concentrations have been inoculated into a saline suspension of Streptococcus mutans and then irradiated using the laser equipment shown in the accompanying drawings. A range of power densities and exposure times were evaluated. Full details of exposure times and laser power densities and dye concentrations assessed are set out in Table 3. Wavelength was 640 nm.

TABLE 3

Dye Concentration [µg/ml]	Dye/Bacteria Suspension Volume [µL]	Laser Power [mW]	Exposure Time [sec]
50	200	80	30
50	200	48	30
50	200	15	30
50	200	80	60
50	200	48	60
50	200	15	60
50	200	15	90
20	200	80	30
20	200	15	30
20	200	80	60
20	200	15	90
20	200	15	60
20	50	40	10
20	50	40	20
20	50	40	30
5	50	40	20
5	50	40	50
5	50	40	80

Dye solutions were made up freshly on each occasion using distilled water. Initially, 100 µl of a saline suspension of Streptococcus mutans was added to a micro well of a microtitre plate. These were derived from Streptococcus mutans NCTC 10449 and suspension was made up to give a concentration of bacteria ranging between 10^8 to 10^9 colony forming units (cfu). [These had an optical density of approximately 0.10]. This solution was then gently agitated for the remainder of the experiment. To this was added either 100µl of TBO or saline. Saline acted as a control. 30 seconds after the addition of the dye, the isotropic probe was immersed in suspension and irradiation carried out at the range of exposure time/power density combinations indicated in Table 3.

Aluminium foil was wrapped around the base of each well on the microtitre plate to prevent laser irradiation affecting wells adjacent to that being treated.

After irradiation, the number of survivors in each well was determined by viable counting on tryptone soya agar. 100µl of liquid from the micro well was removed and diluted progressively tenfold. The diluted suspension was then cultured on the tryptone soya agar plate for 24 hours. Plates were then selected with densities of colony forming units of between 50 – 300 cfu and these were examined for surviving bacteria over the whole of the sample on the plate.

Results

A range of kill levels was achieved with the different combinations of laser power exposure time and dye concentration. This shows that the kill levels required may be achieved at certain laser power/exposure time/dye concentrations. There is a range of combinations, which may be appropriate for use clinically.

Phase 1:

An exposure time of thirty seconds was arbitrarily established as the baseline value to be examined. The laser parameters were defined by the outputs of the machine and 80 and 15mw selected as the outer limits for initial evaluation. Dye

concentrations were fixed at values that had previously been established for penetration of dentine.

The results of the four stages are set out below.

Exposure Time 30 Seconds

Stage 1: Maximum dye concentration and Maximum laser power

Dye Concentration [µg/mL]	Laser Power [mW]	Initial CFU	% Bacterial kill	Mean
50	80	E9-E10	93.11 86.32	89.71

This indicated that there were very substantial kills but total kills were not on the 99.9% value at this particular exposure time.

Stage 2: Minimum dye concentration and Minimum laser power

Dye Concentration [µg/mL]	Laser Power [mW]	Initial CFU	% Bacterial kill	Mean
20	15	1.1E9	0 40.0	20.0

This showed that the minimum output from laser and low dye concentration did not produce adequate kills.

Stage 3: Minimum dye concentration and Maximum laser power

Dye Concentration [µg/mL]	Laser Power [mW]	Initial CFU	% Bacterial kill	Mean
20	80	E9 – E10	99.99 99.99	99.99

This demonstrated that the kill levels, which were required, were achievable at this laser power and dye concentration

Stage 4: Maximum dye concentration and Minimum laser power

Dye Concentration [µg/mL]	Laser Power [mW]	Initial CFU	% Bacterial kill	Mean
50	15	2.1E10 2.8E9	0 14.1	7.05

This shows that maximum dye concentration and minimum laser power produced inadequate kills.

Conclusions

From this is became apparent that successful kills were obtainable with the minimum dye concentration and maximum laser output. Increasing the dye concentration at that laser power reduced the kill rate. From this it was deduced that the maximum dye concentration was in excess of that required and that better results were achievable at lower concentrations. This was confirmed by the stages two and four where although the kill rates were not very high, the higher dye concentrations produced lower kill rates.

Further work was then carried out using different exposure time and laser energy densities in an attempt to establish the range of combinations, which would prove to be effective. For clarity, the results have been reported in sequence for increasing exposure time.

Exposure time : 10 sec

Dye Concentration [µg/mL]	Laser Power [mW]	Initial CFU	% Bacterial kill	Mean
20	40	2.6E7	20.23 52.45	36.34

This was regarded as unsuitable for use. It was not repeated with a lower dye concentration as the increase in kill rates expected was considered to be insufficient to achieve and the exposure time was increased.

Exposure Time : 20 sec

Dye Concentration [µg/mL]	Laser Power [mW]	Initial CFU	% Bacterial kill	Mean
5	40	1.7E7 1.1E8	0 60.3	30.1
20	40	3.0E7 1.8E7	79.36 82.90	81.1

The exposure time of 20 seconds produced kill rates which were substantially higher. At the 20 µg/mL dye concentration tested here 80% kill levels were obtained.

Exposure Time : 50 sec

Dye Concentration [µg/mL]	Laser Power [mW]	Initial CFU	% Bacterial kill	Mean
5	40	7.1E7 1.3E8	84.43 89.85	87.14

The exposure time was extended to 50 seconds with a low dye concentration and low laser power. The kill rates while not being total were extensive. This indicated that the lower dye concentration [5µg/ml] is probably the bottom level that is applicable. It would require a high laser output and longer exposure time for total killing to be achieved.

Exposure Time : 60 sec

Dye Concentration [µg/mL]	Laser Power [mW]	Initial CFU	% Bacterial kill	Mean
20	15	1.2E9 1.1E9	86.32 18.26	52.29
20	80	E9-E10	99.99 99.99	99.99
50	15	1.3E9 2.8E9	12.0 12.32	12.16
50	48	2.3E10 1.3E9	99.76 99.8	99.78
50	80	E9-E10	99.99 99.99	99.99

When the exposure time was extended to 60 seconds with a range of laser powers and dye concentrations, it became apparent that kill rates were high for a range of dye concentrations and laser power outputs. It was apparent that the minimum laser power that was successful in achieving kill rates in the region of 10^9 was 45mW at this time interval.

The accompanying drawings illustrate the manner in which the invention may be carried into effect.

Figure 1 is a schematic longitudinal cross-section through a tooth with one form of optical fibre and tip in place in a root canal;

Figure 2 is a enlarged sectional view of the optical fibre;

Figure 2a is a schematic view of a dental handpiece fitted with an optical fibre and tip and a tube for introducing photosensitiser into a root canal;

Figure 3 is a section through a single dose device for delivering a photosensitiser solution into the root canal;

Figure 4 is a perspective view of a laser housing connected to a dental handpiece;

Figure 5 is a view in the direction of the arrow "X" in Figure 4; and

Figure 6 is a graph showing the effect of increasing the light transmission of carious dentine by demineralisation with EDTA.

The tooth (1) is first drilled to access the entrance (2) to the infected root canal (3), and the canal opened up and debrided using conventional instruments. Loose debris is suctioned away and, optionally, the canal is flushed with a hypochlorite solution and then with water. A photosensitiser solution, e.g. Toluidine blue O, in dilute aqueous solution (concentration about 20μg/ml) is then introduced into the root

canal using a fine-tipped syringe having an obliquely angled tip, or a disposable dispenser such as shown in Figures 2a or 3. Referring to Figure 3, the dispenser comprises a thin-walled cannula (10) having a reservoir (11) for photosensitiser solution attached to its proximal end. The connection between the reservoir and the cannula is sealed with a frangible membrane 12. At its distal end, the cannula is perforated with small holes (13) which permit the escape of liquid from the cannula. In use, the cannula is inserted into the root canal until the distal end is close to the apex of the canal. Photosensitiser is discharged into the root canal by pressing on the reservoir (11), thus causing the membrane to rupture and liquid to flow out of the distal end and through the perforations (13). The perforations (13) ensure that the walls of the root canal are wetted with photosensitiser solution. Preferably, the photosensitiser is allowed to remain in contact with the root canal to permit the photosensitiser to be absorbed by bacteria within the canal, normally about 20 to 40 seconds. The dispenser is then removed and an optical fibre (20), as shown in Figure 2, is introduced into the root canal (3) and laser light having a wavelength of about 630/640 nm guided into the canal.

As can be seen best in Figure 2, the optical fibre is formed with a transparent distal spherical portion (21), typically of about 800 microns diameter. This has the effect of diffusing light passed down the fibre and ensures that light emerging at the tip (21) is scattered uniformly around and in upward and downward directions in the root canal.

It may be desirable to move the tip of the optical fibre relatively to the canal, either stepwise or continuously, while irradiating the interior of the canal. For

example, the tip may be inserted initially to the apex of the canal and then gradually withdrawn, while irradiating the canal. This may be facilitated by the fibre carrying incremental markings on its external surface similar to the tip dimensions. The operator may withdraw the tip incrementally, using the marks to ensure that irradiation of the photosensitiser is carried out over the whole canal length. Instead of an optical fibre having a spherical tip, a fibre having a generally cylindrical distal part may be used. For example, the tip may comprise a 3mm long cylindrical tip having a diameter of about 200 to 500 microns, preferably 200 to 300 microns. This has approximately the same area as the spherical tip referred to above.

The optical fibre itself typically has a diameter of about 200 to 800 microns, preferably 200 to 500 microns. The fibre may be protected by an outer tube of plastic or metal, with the tip projecting from the outer protective tube. The outer tube may be tapered in the same sense as the prepared root canal.

Figure 2(a) shows a developed form of the system shown in Figures 1, 2 and 3. The handpiece (42) has a "plug in" optic fibre (4) having an isotropic tip (5). The fibre is received as a snap-fit in the handpiece (42) and is optically connected through the handpiece to a laser source in the console (41). Surrounding the optic fibre is a hollow tube (6). Contained within the handpiece are reservoirs (7) and (8) filled, respectively, with photosensitiser dye and sealant composition. Feed tubes (9) and (10) connect the reservoirs to the tube (6). The reservoirs may be squeezable pouches so that on applying pressure to the respective pouch, dye or fluid resin can be injected as required into the tube (6) and thence into the prepared canal (2) in the tooth. Preferably, the reservoirs, fibre tip and tube are disposable.

A more developed version of the laser console and a dental handpiece carrying the optical fibre is shown in Figures 4 and 5. Figure 4 shows a perspective view of the laser housing (41) linked to a dental handpiece (42). An optical fibre (43) is held in the part of the handpiece which will be introduced into the patient's mouth. The optical fibre (43) is a disposable "plug in" element which carries an isotropic tip as described above. Housing (41) contains laser generating equipment whose output is connected to a flexible heavy duty optical fibre within the handpiece, the output from the fibre (44) is connected to the disposable fibre (43). Two laser sources may be accommodated in the housing (41), one capable of emitting laser light at a wavelength of about 670 nm for effecting the photosensitising treatment, and the other capable of emitting laser light for curing the resin sealant. Light guides and a beam splitter may be provided so that light from each laser source can be selectively switched to the tip (43). The fibre tip may be changed after the photosensitising treatment has been carried out and fresh tip plugged into the handpiece in order to carry out curing of the resin sealant.

Figure 5 shows a control panel (45) having a touch screen (46) for programming the laser power and duration of treatment. For convenience, the apparatus can be made in portable form and incorporate a rechargeable battery.

After the photosensitiser has been irradiated with laser light for a sufficient period to ensure sterilisation of the interior of the canal (usually 30 seconds to 1 minute at a laser power of between 40 - 80 mW), the optical fibre is removed.

It may be desirable at this point to aspirate photosensitiser from the canal.

A fluid sealing or filling composition is then introduced into the canal. For this purpose, a unit dose dispenser such as that shown in Figure 2a may be used. An optical fibre such as shown in Figure 2a may then be introduced into the root canal and light passed down the fibre to cure the sealant material. This will hermetically seal the root canal from reinfection. The sealant material may incorporate a radio-opaque filler material, such as a barium or strontium salt, e.g. the fluoride. It may further contain amine fluoride. The projecting part of the optical fibre may then be cut off and the access hole may be filled with a conventional dental filling material such as an amalgam or glass ionomer resin.

Experiments with slices of dentine cut from extracted human teeth have shown that it is desirable to pretreat a canal with a demineralisation solution, e.g. of EDTA prior to the photosensitisation treatment. Even a short pre-treatment with EDTA, e.g. as a 0.1 molar aqueous solution, substantially increases the distance through which the laser light can pass. Even pre-treatment of the dentine with 0.1 molar EDTA or other demineralisation solution for as little as 15 seconds increased the depth of light transmission and dye penetration significantly. This is an important finding and enables the dentist to be confident that bacteria has been killed in passages leading from the canal in the treated tooth. The effect of demineralisation treatment on the light transmission and dye absorption is shown graphically in Figure 5. The effect of the demineralisation additive appears to be self-limiting in that the maximum demineralised area extends essentially only to the boundary of the dentine affected by a carious lesion.

Alternatively, the sterilised canal may be sealed by means of gutta percha plugs supported on a plastic or metal rod-like carrier as described in EPA 0337024 or USA 5149268.

CLAIMS:-

1. A method of treating a dental root canal which comprises the steps of:-

(a) gaining access to the root canal;

(b) introducing a flowable photosensitiser into the root canal;

(c) activating the photosensitiser by exposing the walls of the root canal to light via an optical fibre within the root canal to kill bacteria within the root canal and pulp chamber; and

(d) obturating the root canal.

2. A method according to claim 1 wherein the root canal is obturated with gutta percha, silver or titanium points.

3. A method according to claim 2 in which the root canal is obturated with an obturation device comprising gutta percha carried on a rod-like carrier, the device being shaped and dimensioned so that on forcing it into the canal, the gutta percha is deformed and fills the canal.

4. A method according to claim 1 in which the root canal is obturated with a curable filling material.

5. A method according to claim 4 wherein the curable filling material is cured by irradiation with light through an optical fibre within the root canal.

6. A method according to claim 5 wherein the same optical fibre is used for activating the photosensitiser and the curable filler material.

7. A method according to any one of the preceding claims wherein the optical fibre has a substantially isotropic tip.

8. A method according to any one of the preceding claims in which the optical fibre has a spherical or cylindrical portion at or close to the distal end to spread radiation around and along the canal.

9. A kit of parts for treating a dental root canal which comprises:-

(a) a flowable photosensitiser;

(b) an optical fibre having a portion at or close to the distal end which is shaped to spread radiation around and along the canal, said fibre being adapted for introduction into a root canal so that the tip is capable of reaching the apical third of the root canal, said optical fibre being connectable proximally with means for generating laser light; and

(c) obturating means for sealing the canal.

10. A kit according to claim 9 wherein the flowable sensitiser comprises a dilute aqueous solution of toluidine blue.

11. A kit according to claim 9 wherein the obturating means comprises a preformed plug of gutta percha or silver or titanium points.

12. A kit according to any one of the preceding claims wherein the flowable sensitiser is contained in a cartridge which includes a delivery tube for introducing the photosensitiser into the canal.

13. A kit according to claim 9 wherein the obturating means comprises a flowable, curable sealing composition.

14. A kit according to any one of claims 8 to 13 wherein the distal portion of the optical fibre comprises a translucent polymer composition containing a minor

amount of a dispersed pigment sufficient to cause light transmitted by the fibre to be scattered around the canal.

15. A kit according to any one of claims 8 to 14 wherein the distal portion of the optical fibre is formed by polymerising a light-curable polymerisable composition on an end of the optical fibre.

16. Use in the manufacture of materials for sterilising and sealing a dental root canal of a kit of parts comprising:

(a) a flowable photosensitiser;

(b) an optical fibre which is shaped and dimensioned to pass into a root canal to the region of the apex thereof, said optical fibre being connectable proximally with means for generating laser light at a wavelength which is capable of being absorbed by the photosensitiser and said optical fibre having a distal portion which is shaped to spread the laser light around and along the canal; and

(c) obturating means for sealing the canal.

17. Use according to claim 16 in which the photosensitiser is an aqueous dye.

18. Use according to claim 17 in which the photosensitiser is toluidine blue in aqueous solution.

19. Use according to any one of claims 16 to 18 in which the obturating means comprises gutta percha supported on a rod-like support.

20. Use according to any one of claims 16 to 18 in which the obturating means comprises a light curable resin composition.

21. Use according to any one of claims 16 to 20 wherein the distal portion of the optical fibre comprises a translucent polymer composition containing a minor amount of a dispersed pigment sufficient to cause light transmitted by the fibre to be scattered around the canal.

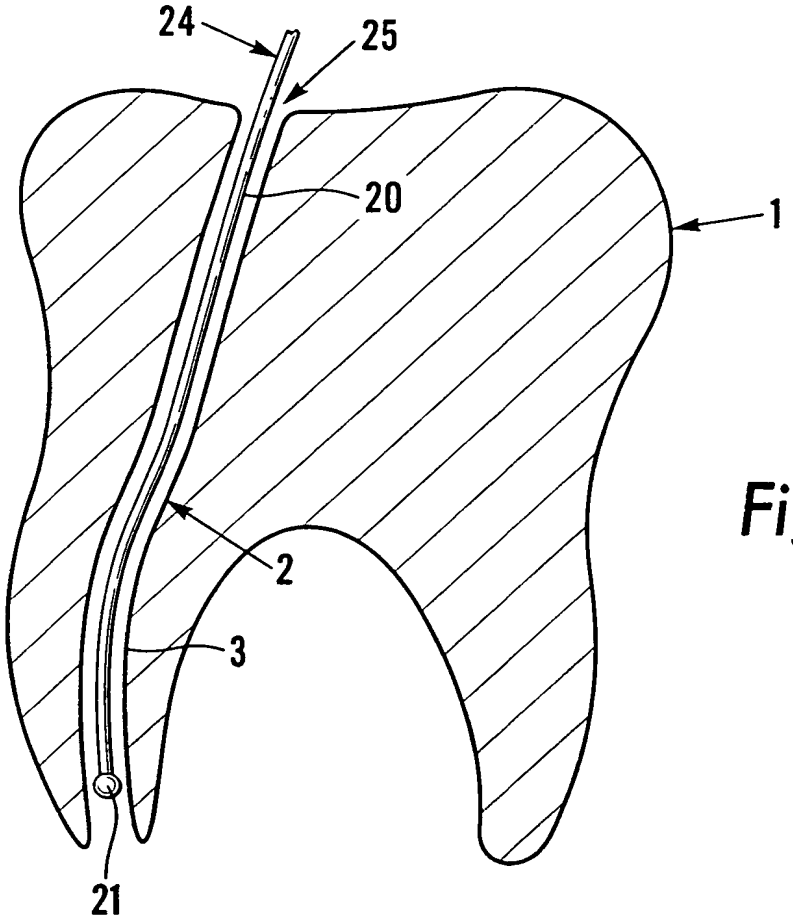


Fig.1

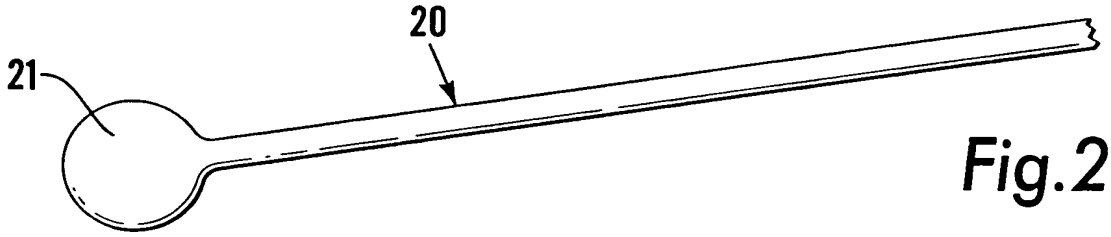


Fig.2

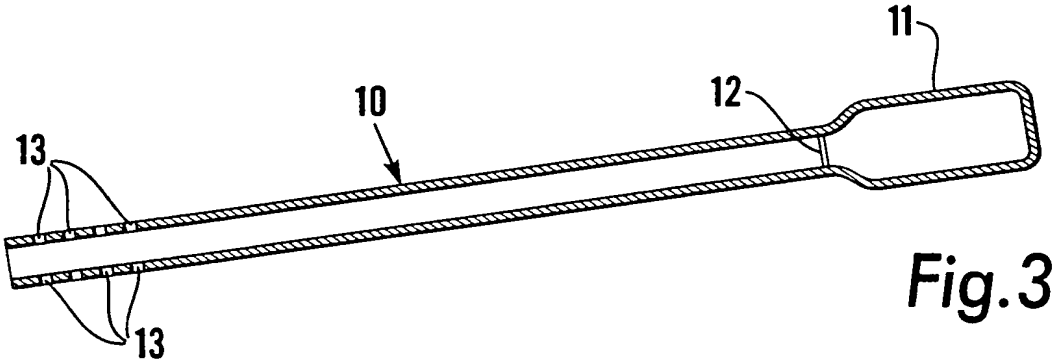


Fig.3

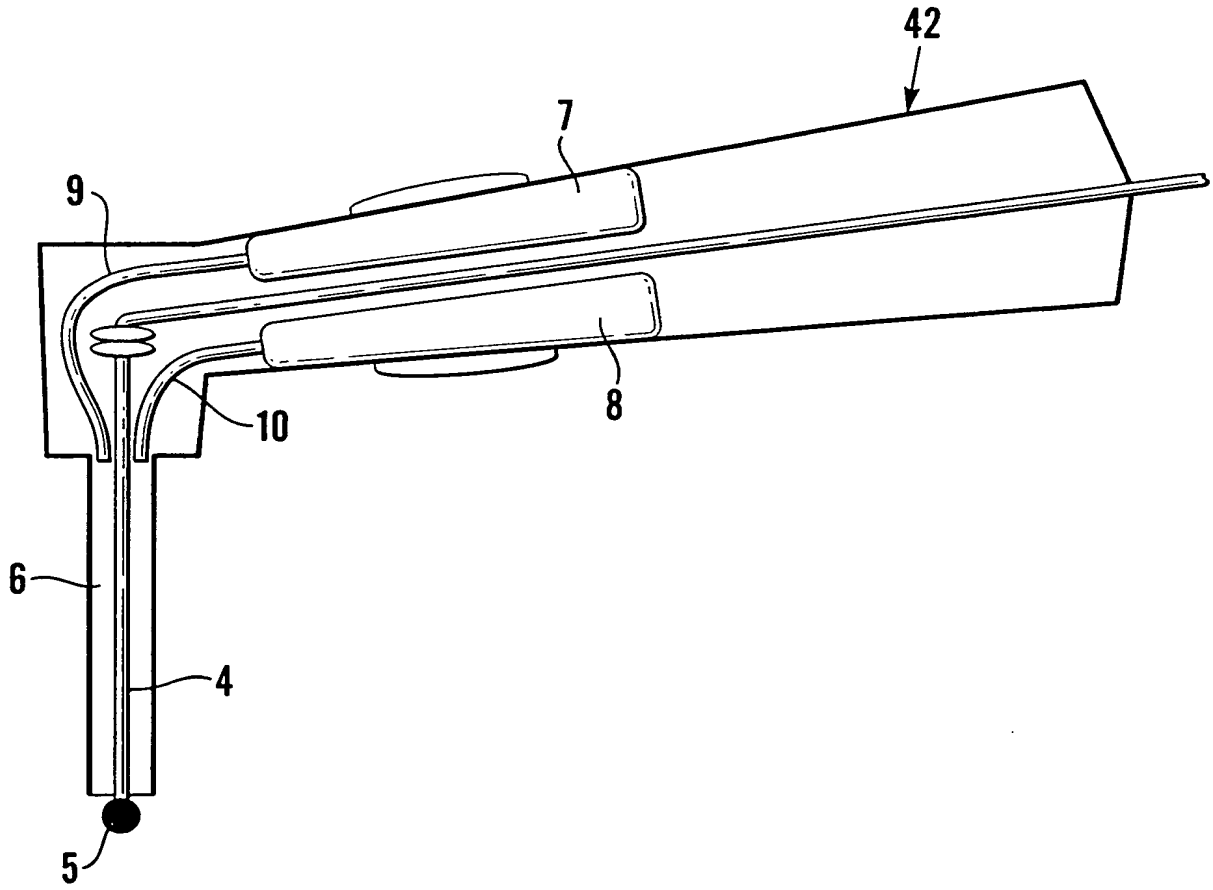


Fig.2a

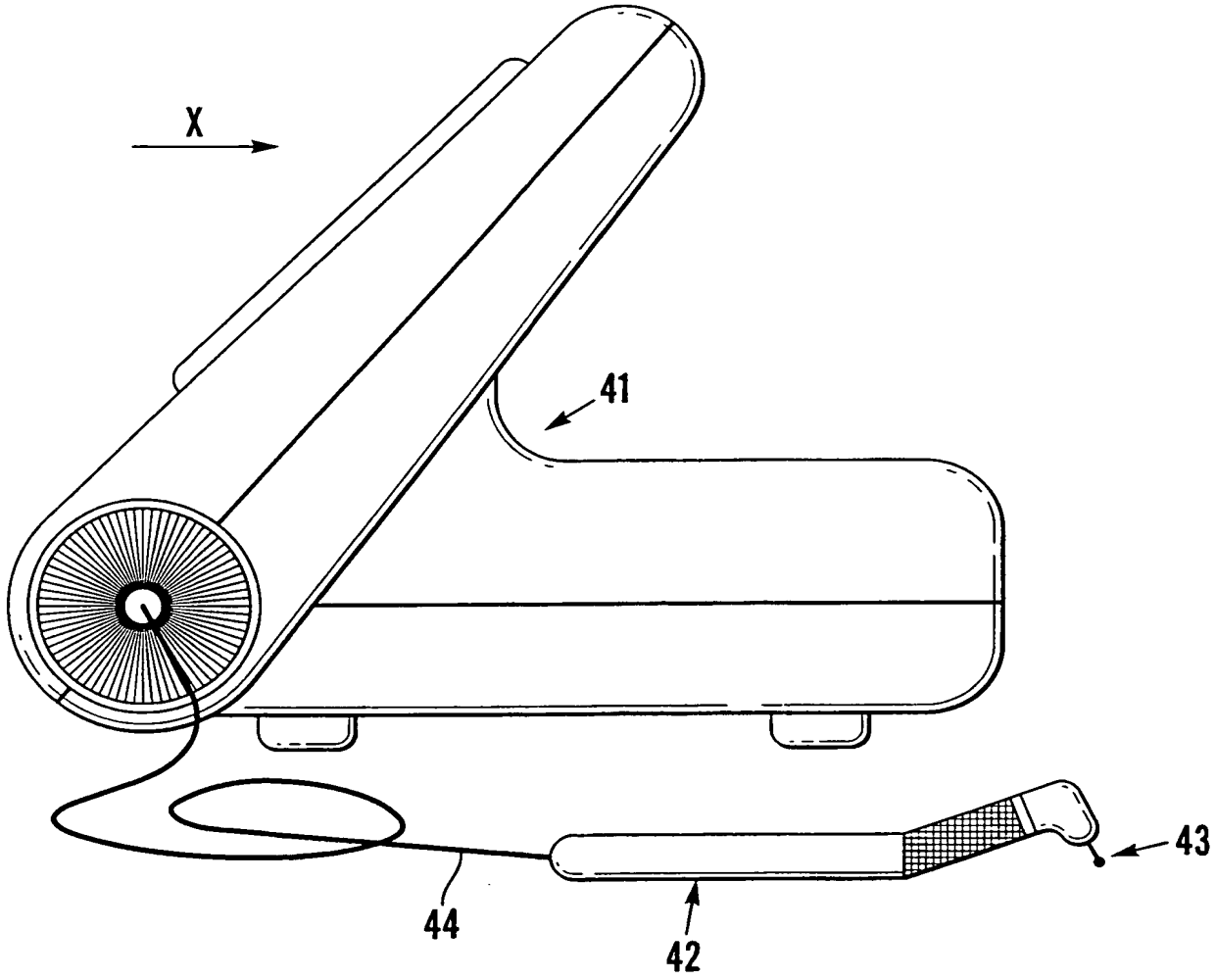


Fig.4

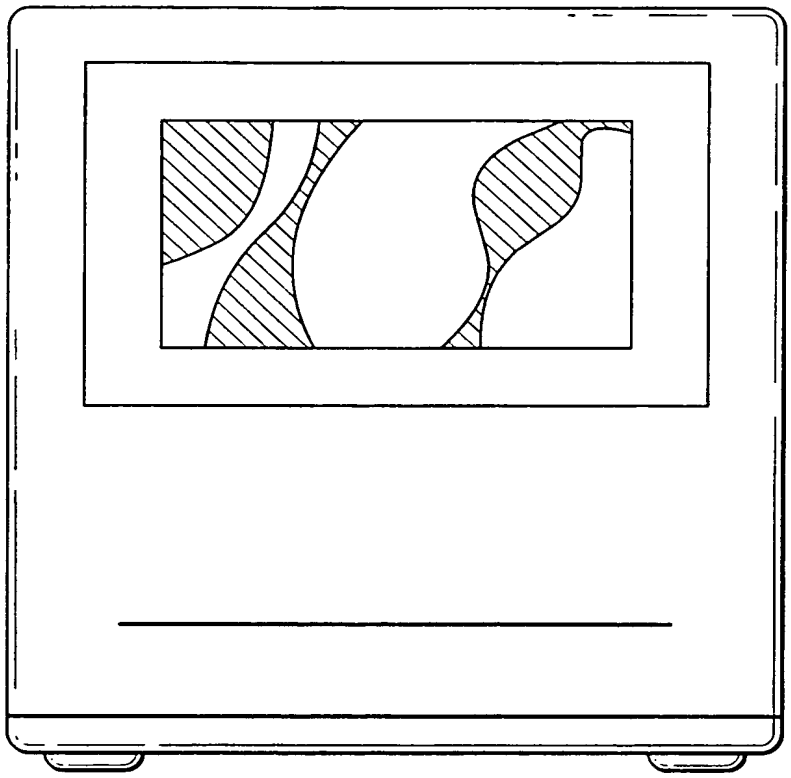
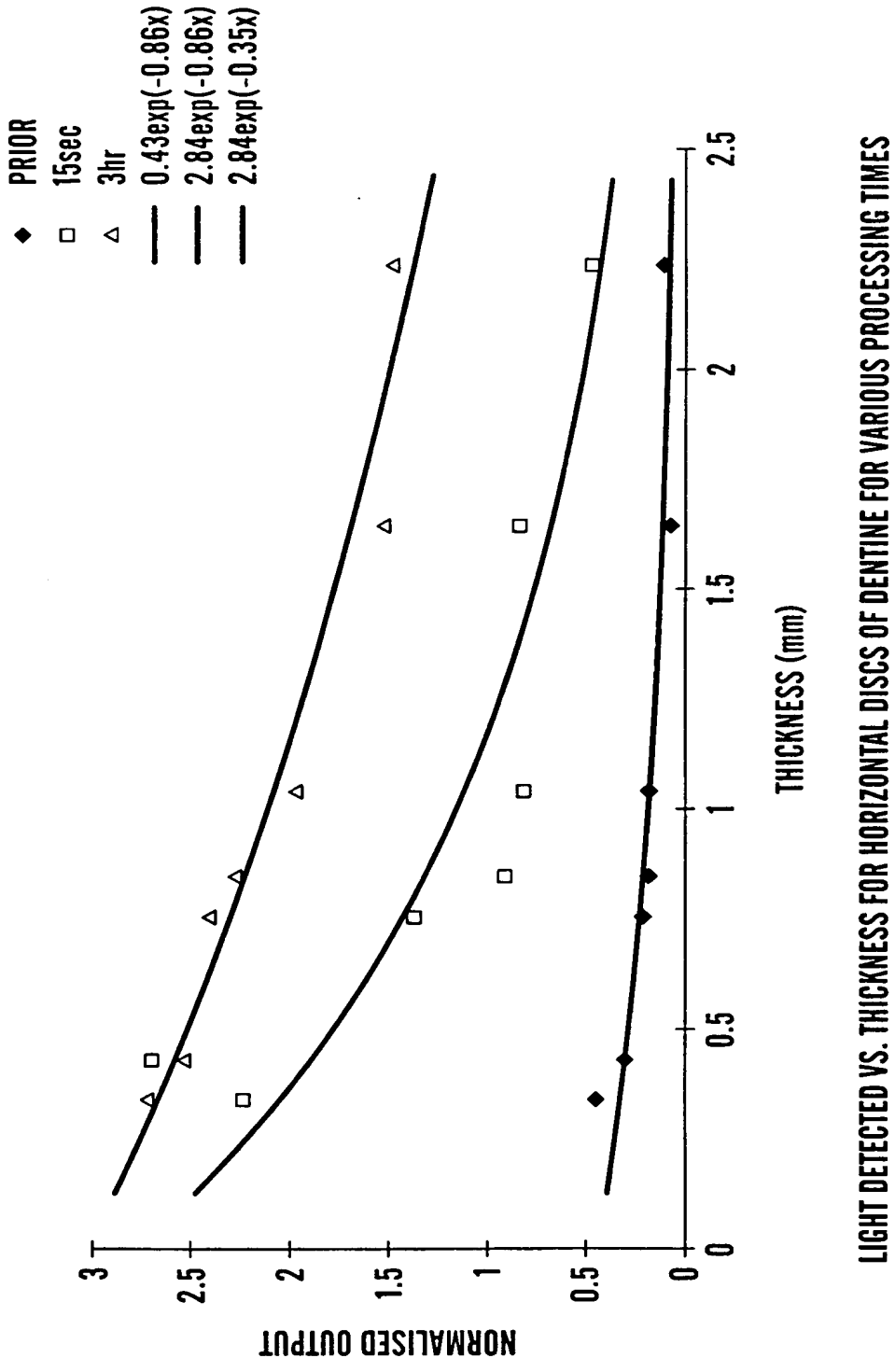


Fig.5



LIGHT DETECTED VS. THICKNESS FOR HORIZONTAL DISCS OF DENTINE FOR VARIOUS PROCESSING TIMES

Fig.6

INTERNATIONAL SEARCH REPORT

International Application No
PCT/GB 00/02133

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61C5/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61C

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0 830 851 A (CEDARS-SINAI MEDICAL CENTER) 25 March 1998 (1998-03-25) the whole document	9,13,16, 20
A	EP 0 830 852 A (CEDARS-SINAI MEDICAL CENTER) 25 March 1998 (1998-03-25) column 12, line 26 - line 54; figures 21-24	9,13,16, 20
A	WO 93 21992 A (INSTITUTE OF DENTAL SURGERY) 11 November 1993 (1993-11-11) page 5, line 9	9,10, 16-18
A	EP 0 938 875 A (MARTELLI) 1 September 1999 (1999-09-01) the whole document	9,13,16, 20,21

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
14 September 2000	21/09/2000

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Vanrunxt, J

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International Application No
PCT/GB 00/02133

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
A	WO 92 16174 A (RIAZI) 1 October 1992 (1992-10-01) the whole document	9,11

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Information on patent family members

Inter[illegible] Application No
PCT/GB 00/02133

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
EP 830851	A	25-03-1998	US	5503559 A	02-04-1996
			EP	0830852 A	25-03-1998
			AT	170389 T	15-09-1998
			DE	69413047 D	08-10-1998
			DE	69413047 T	08-04-1999
			EP	0720452 A	10-07-1996
			JP	9505213 T	27-05-1997
			WO	9508962 A	06-04-1995
EP 830852	A	25-03-1998	US	5503559 A	02-04-1996
			EP	0830851 A	25-03-1998
			AT	170389 T	15-09-1998
			DE	69413047 D	08-10-1998
			DE	69413047 T	08-04-1999
			EP	0720452 A	10-07-1996
			JP	9505213 T	27-05-1997
			WO	9508962 A	06-04-1995
WO 9321992	A	11-11-1993	AT	159661 T	15-11-1997
			CA	2134479 A	11-11-1993
			DE	69314949 D	04-12-1997
			DE	69314949 T	26-03-1998
			EP	0637976 A	15-02-1995
			JP	8503383 T	16-04-1996
			US	5611793 A	18-03-1997
EP 938875	A	01-09-1999	IT	MI980385 A	26-08-1999
WO 9216174	A	01-10-1992	US	5215461 A	01-06-1993
			AU	1872092 A	21-10-1992

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	FOR FURTHER ACTION	see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.
DCW/AKW		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/GB 00/ 02133	02/06/2000	04/06/1999
Applicant		
DENFOTEX LTD		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 5 sheets.

[X] It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

   a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   [ ] the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

   b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

   [ ] contained in the international application in written form.

   [ ] filed together with the international application in computer readable form.

   [ ] furnished subsequently to this Authority in written form.

   [ ] furnished subsequently to this Authority in computer readble form.

   [ ] the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   [ ] the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. [X] **Certain claims were found unsearchable** (See Box I).

3. [ ] **Unity of invention is lacking** (see Box II).

4. With regard to the **title,**

   [X] the text is approved as submitted by the applicant.

   [ ] the text has been established by this Authority to read as follows:

5. With regard to the **abstract,**

   [ ] the text is approved as submitted by the applicant.

   [X] the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No. 1

   [X] as suggested by the applicant.

   [ ] because the applicant failed to suggest a figure.

   [ ] because this figure better characterizes the invention.

   [ ] None of the figures.

Box III TEXT OF THE ABSTRACT (Continuation of item 5 of the first sheet)

The abstract is modified as follows:

A dental root canal is treated by a flowable photosensitiser and thereafter filled by obturating means for sealing the canal. During this treatment an optical fibre is introduced into the root canal, said optical fibre being connectable proximally with means for generating laser light.

INTERNATIONAL SEARCH REPORT

International Application No
GB 00/02133

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61C5/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61C

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0 830 851 A (CEDARS-SINAI MEDICAL CENTER) 25 March 1998 (1998-03-25) the whole document ---	9,13,16, 20
A	EP 0 830 852 A (CEDARS-SINAI MEDICAL CENTER) 25 March 1998 (1998-03-25) column 12, line 26 - line 54; figures 21-24 ---	9,13,16, 20
A	WO 93 21992 A (INSTITUTE OF DENTAL SURGERY) 11 November 1993 (1993-11-11) page 5, line 9 ---	9,10, 16-18
A	EP 0 938 875 A (MARTELLI) 1 September 1999 (1999-09-01) the whole document ---	9,13,16, 20,21

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
14 September 2000	21/09/2000

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Vanrunxt, J

3

Form PCT/ISA/210 (second sheet) (July 1992)

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
A	WO 92 16174 A (RIAZI) 1 October 1992 (1992-10-01) the whole document -----	9,11

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
GB 00/02133

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
EP 830851	A	25-03-1998	US	5503559 A	02-04-1996
			EP	0830852 A	25-03-1998
			AT	170389 T	15-09-1998
			DE	69413047 D	08-10-1998
			DE	69413047 T	08-04-1999
			EP	0720452 A	10-07-1996
			JP	9505213 T	27-05-1997
			WO	9508962 A	06-04-1995
EP 830852	A	25-03-1998	US	5503559 A	02-04-1996
			EP	0830851 A	25-03-1998
			AT	170389 T	15-09-1998
			DE	69413047 D	08-10-1998
			DE	69413047 T	08-04-1999
			EP	0720452 A	10-07-1996
			JP	9505213 T	27-05-1997
			WO	9508962 A	06-04-1995
WO 9321992	A	11-11-1993	AT	159661 T	15-11-1997
			CA	2134479 A	11-11-1993
			DE	69314949 D	04-12-1997
			DE	69314949 T	26-03-1998
			EP	0637976 A	15-02-1995
			JP	8503383 T	16-04-1996
			US	5611793 A	18-03-1997
EP 938875	A	01-09-1999	IT	MI980385 A	26-08-1999
WO 9216174	A	01-10-1992	US	5215461 A	01-06-1993
			AU	1872092 A	21-10-1992

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

WOODCRAFT, David C.
BROOKES & MARTIN
High Holborn House
52/54 High Holborn
London WC1V 6SE
GRANDE BRETAGNE

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Rule 71.1)

Date of mailing *(day/month/year)*	18.09.2001
Applicant's or agent's file reference: DCW/AKW	**IMPORTANT NOTIFICATION**

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/GB00/02133	02/06/2000	04/06/1999

Applicant: DENFOTEX LTD et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301). D 04.12.2001

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

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European Patent Office
D-80298 Munich
Tel. +49 89 2399 - 0 Tx: 523656 epmu d
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PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
DCW/AKW		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/GB00/02133	02/06/2000	04/06/1999

International Patent Classification (IPC) or national classification and IPC
A61C5/00

Applicant
DENFOTEX LTD et al.

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 8 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 4 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement
   - VI ☐ Certain documents cited
   - VII ☒ Certain defects in the international application
   - VIII ☒ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
03/11/2000	18.09.2001

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB00/02133

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:
Description, pages:

1-29 as originally filed

Claims, No.:

1-23 as received on 27/07/2001 with letter of 23/07/2001

Drawings, sheets:

1/5-5/5 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:

☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 1-8, 16, 17-22.

because:

☒ the said international application, or the said claims Nos. 1-8, 17-22 relate to the following subject matter which does not require an international preliminary examination (*specify*):
see separate sheet

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☒ the claims, or said claims Nos. 16 are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the said claims Nos. .

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N) Yes: Claims 9-15

	No:	Claims	
Inventive step (IS)	Yes:	Claims	14
	No:	Claims	9-13, 15
Industrial applicability (IA)	Yes:	Claims	9-15
	No:	Claims	

2. Citations and explanations
see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:
see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:
see separate sheet

Reference is made to the following documents:

D1: EP-A-0 830 850 (KURARAY CO.) 25 March 1998
D2: WO 93 21992 A (INSTITUTE OF DENTAL SURGERY) 11 November 1993
D3: EP-A-0 938 875 (MARTELLI) 1 September 1999

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The independent method claim 1, as well as its dependent claims 2-8 clearly refer to a method for treatment of the human body by therapy. The international preliminary examining authority is not required to carry out an international preliminary examination on such claims (Rule 67.1 (iv) PCT).

2. According to the decision of the Enlarged Board of Appeal (G5/83, OJ 1985, 64), second medical use claim would have to be directed to the use of a substance or composition for the manufacture of a medicament for a specified new and inventive therapeutic application. Throughout this decision, reference is only made to chemical substances and compositions, not to materials and/or parts. However, in this case the optical fibre is not a substance or composition, nor are the "materials" a medicament. Therefore, the independent claim 17 is not regarded as a second medical use claim and no international preliminary examination will be carried out on the independent claim 17 and its dependent claims 18-22.

3. The amendments filed with the letter dated 23 July 2001 introduce subject-matter which extends beyond the content of the application as filed, contrary to Article 34(2)(b) PCT.
   The new dependent claim 16 is not supported by the description, since nowhere in the description is mentioned that "the isotropic tip.. Is capable of irradiating...in an arc of up to 360°".

Re Item VIII

Certain observations on the international application

1. Claim 9 does not meet the requirements of Article 6 PCT since matter for which protection is sought is not clearly defined.

   The feature that "the optical fibre has a portion... which is shaped to spread radiation around and along the wall" describes only a result to be achieved. According to the Guidelines for Exam. C-III, 4.7, "claims which attempt to define the invention by a result to be achieved... may be allowed if the invention either can only be defined in such terms or cannot otherwise be defined more precisely". However, in this case it is clear that the end portion can be defined by its technical characteristics (see f.i. description, page 9).

2. Claim 14 is not clear. The characterising part of the optical fibre " a minor amount of dispersed pigment sufficient to cause..." contains the relative term "minor", which has no well-recognised meaning. Also the term "a minor amount ... sufficient to cause" is specified in terms of the result to be achieved. Therefore, the claim 14 does not fulfill the requirements of Art. 6.

3. The new independent claim 23 is not clear either. It is not clear from the sentence "use, - in the manufacture of a kit..., the kit comprising...- " what is the object to be used. Therefore, the claim 23 does not fulfill the requirements of Art. 6.

Re Item V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Insofar as claim 9 can be understood (see Section VIII), it discloses the document D2 discloses: a kit of parts for use in sterilising and sealing a dental root canal (page 2, lines 1-7), said kit of parts comprising (page 10, line 21 - page 11, line 5): a flowable photosensitiser which is absorbed by bacteria (page 9, lines 22-27), an optical fibre being connectable proximally with means for generating laser light capable of being absorbed by the photosensitiser (page 2, lines 1-7) and obturating means for sealing the canal (page 10, line 21- page 11, line 5).
   The subject-matter of claim 9 differs from the kit as disclosed in D2 in that the optical fibre has a portion at or close to the distal end which is shaped to spread radiation around and along the canal, the fibre being adapted for introduction into a root canal

so that the tip is capable of reaching the apical third of the root canal.
The document D1 discloses the use of an optical fibre in a dental application, the optical fibre being used to irradiate a photosensitizer and having these additional technical features (page 4, line 13-18, 34-38, page 8, lines 14-19, Fig. 1B). The feature that the distal end is "shaped to spread radiation around and along the canal" is so loosely worded, that it is even fulfilled by the distal end of the optical fibre as disclosed in D1 (page 3, lines 47-51).
The applicant is right in his remark that in D1 scattering of the light is caused by a component of the dental composition and not as a result of the shape and structure of the distal end of the fibre. However, these technical features, making the distinction between the invention and the state of the art, are not part of the subject-matter of claim 9.
Therefore the subject-matter of independent claim 9 does not involve an inventive step (Article 33(3) PCT).

2. The use of a dilute aqueous solution of toluidine blue as flowable sensitiser is known from D2 (page 4, lines 22-28, page 5, line 9).
The document D3 discloses obturating means like gutta percha or silver or titanium points (page 6, lines 1-7).
The technical feature that "the flowable sensitiser is contained in a cartridge which includes a delivery tube" is a commonly used simple way of storing and supplying a liquid.
The document D1 also discloses obturating means, comprising a flowable, curable sealing composition (page 7, lines 13-41).
Since these all products were used in dentistry for sterilising and sealing purposes, the skilled person will regard it as normal to combine such features without the exercise of an inventive step. Therefore the additional technical features of claims 10-13 lack an inventive step (Article 33(3) PCT).

3. From document D1 it is known that the surface of the part of the optical fibre being in the resin, i.e. the distal part, can be formed by coating the fibre with different products, among which are polymers and rubbers (page 5, lines 36-37). The additional technical feature of claim 15 consists only in the selection of a non-specified light-curable polymerisable composition. Therefore, no inventive step is

present in claim 15.

4. Notwithstanding lack of clarity mentioned in Re Item VIII, the additional technical feature of claim 14, "the distal portion of the optical fibre comprises a translucent polymer composition containing a dispersed pigment" appears to be new and inventive.

Re Item VII

Certain defects in the international application

1. Independent claim 9 should have been worded in the two-part form (Rule 6.3(b) PCT), incorporating in the preamble those features known in combination from the prior art (document D2) and the remaining features in the characterizing part.

2. Reference signs not appearing in the description shall not appear in the drawings, and vice versa (Rule 11.13(l)). This requirement is not met in view of the reference signs 45 and 46 in Fig. 5 .

It appears that the invention claimed in this application is fairly the same as the invention claimed in the PCT-application PCT/BG00/01433.

CLAIMS:-

1. A method of treating a dental root canal which comprises the steps of:-

(a) gaining access to the root canal;

(b) introducing a flowable photosensitiser into the root canal;

(c) activating the photosensitiser by exposing the walls of the root canal to light via an optical fibre within the root canal to kill bacteria within the root canal and pulp chamber; and

(d) obturating the root canal.

2. A method according to claim 1 wherein the root canal is obturated with gutta percha, silver or titanium points.

3. A method according to claim 2 in which the root canal is obturated with an obturation device comprising gutta percha carried on a rod-like carrier, the device being shaped and dimensioned so that on forcing it into the canal, the gutta percha is deformed and fills the canal.

4. A method according to claim 1 in which the root canal is obturated with a curable filling material.

5. A method according to claim 4 wherein the curable filling material is cured by irradiation with light through an optical fibre within the root canal.

6. A method according to claim 5 wherein the same optical fibre is used for activating the photosensitiser and the curable filler material.

7. A method according to any one of the preceding claims wherein the optical fibre has a substantially isotropic tip.

8. A method according to any one of the preceding claims in which the optical fibre has a spherical or cylindrical portion at or close to the distal end to spread radiation around and along the canal..

9. A kit of parts for use in sterilising and sealing a dental root canal (2), said kit of parts comprising:-

(a) a flowable photosensitiser which is absorbed by bacteria;

(b) an optical fibre (4,20) having a portion (5,21) at or close to the distal end which is shaped to spread radiation around and along the canal, said fibre being adapted for introduction into a root canal so that the tip is capable of reaching the apical third of the root canal, said optical fibre being connectable proximally with means (41) for generating laser light capable of being absorbed by the photosensitiser; and

(c) obturating means for sealing the canal.

10. A kit according to claim 9 wherein the flowable sensitiser comprises a dilute aqueous solution of toluidine blue.

11. A kit according to claim 9 wherein the obturating means comprises a preformed plug of gutta percha or silver or titanium points.

12. A kit according to any one of claims 9 to 11 wherein the flowable sensitiser is contained in a cartridge (7,11) which includes a delivery tube (9,10) for introducing the photosensitiser into the canal.

13. A kit according to claim 9 wherein the obturating means comprises a flowable, curable sealing composition.

14. A kit according to any one of claims 8 to 13 wherein the distal portion of the optical fibre comprises a translucent polymer composition containing a minor amount of a dispersed pigment sufficient to cause light transmitted by the fibre to be scattered around the canal.

15. A kit according to any one of claims 8 to 14 wherein the distal portion of the optical fibre is formed by polymerising a light-curable polymerisable composition on an end of the optical fibre.

16. A kit according to any one of claims 8 to 15 wherein the optical fibre (4,20) has a substantially isotropic tip (5,21) so that it is capable of irradiating the interior of the canal in an arc of up to 360°.

17. Use in the manufacture of materials for sterilising and sealing a dental root canal (2) of a kit of parts comprising:

(a) a flowable photosensitiser which is absorbed by bacteria;

(b) an optical fibre (4,20) which is shaped and dimensioned to pass into a root canal to the region of the apex thereof, said optical fibre being connectable proximally with means for generating laser light at a wavelength which is capable of being absorbed by the photosensitiser and said optical fibre having a distal portion (5,21)which is shaped to spread the laser light around and along the canal; and

(c) obturating means for sealing the canal.

18. Use according to claim 17 in which the photosensitiser is an aqueous dye.

19. Use according to claim 18 in which the photosensitiser is toluidine blue in aqueous solution.

20. Use according to any one of claims 17 to 19 in which the obturating means comprises gutta percha supported on a rod-like support.

21. Use according to any one of claims 17 to 19 in which the obturating means comprises a light curable resin composition.

22. Use according to any one of claims 17 to 21 wherein the distal portion of the optical fibre comprises a translucent polymer composition containing a minor amount of a dispersed pigment sufficient to cause light transmitted by the fibre to be scattered around the canal.

23. Use, in the manufacturing of a kit of parts for use in sterilising and sealing a dental root canal (2), the kit of parts comprising:-

(a) a flowable photosensitiser comprising a photosensitive dye;

(b) an optical fibre (4,20) which is connectable proximally to means for generating laser light at a wavelength capable of being absorbed by the photosensitiser and which has a substantially isotropic distal tip (5,21) which is free from an internally reflecting layer, the tip (5) being shaped and dimensioned so that it can be moved along the canal to activate the photosensitiser; and

(c) obturating means for sealing the canal comprising a preformed plug of gutta percha or silver or titanium points or a flowable, photo-curable sealing composition.

METHOD AND APPARATUS FOR FILLING A DENTAL ROOT CANAL

This invention relates to the treatment of a dental root canal including the obturation of the canal.

Background of the Invention

There are a number of situations in which treatment of root canals in teeth is indicated. The tissue lying within the tooth structure, the dental pulp, may become diseased as a result of dental caries or the cells and tissue may be traumatised or atrophy. As a result of this, the pulp tissue may die and/or become infected. This leads to death of the pulp. While it has been common practice to extract the tooth, use of the tooth can be preserved by the removal of the diseased tissue and sealing the cleaned and sterilised canal. The operation of mechanically removing the diseased pulp is technically difficult and require the accessing of the canal and removing infected tissue, which may be at or near the apex of the root of the tooth. The treatment becomes more complex as the anatomy of the root canal becomes more complex and the canals themselves become narrower.

Conventional endodontic treatment involves first gaining access to the pulp chamber by removing the overlying enamel and dentine. Once the pulp chamber is exposed, the entrances to the root canals are then located and enlarged. The length of the root canal is calculated from a diagnostic radiograph or by means of an apex locator and the canal is instrumented using files and/or reamers of increasing size. These instruments are designed to remove the internal surface of the root canal by rasping and cutting the dentine walls. The dentine walls have small holes where the dentine forming cell processes track into the dentine. These holes are sites where

bacteria can settle and proliferate. It is these areas which are reduced by mechanical debriding of the internal surface of the root canal. To achieve this, the reamers and files are used to produce a root canal that, near the apex, is matched in size to the obturating device. The internal diameter of the canal is enlarged so that the cavities in the root wall are reduced in size and the canal is mechanically cleaned.

Medicaments may be used to chemically kill the bacteria; these are usually disinfectants and anti-bacterials such as hypochlorite solution or antibiotic pastes. These may be introduced into the root canal after initial mechanical debridement. These medicaments and mechanical methods of removal of tissue are designed to produce a root canal which is free of bacteria and other contaminants. Conventional procedures are time consuming and difficult to carry out since they require careful and extensive mechanical debridement of the canal walls and use of copious volumes of irrigants such as aqueous sodium hypochlorite to flush out the canal. The more posterior the tooth situation within the mouth the greater the risk of failure to achieve the objectives, since the root canals morphology becomes more convoluted and adequate access becomes more difficult to achieve.

Summary of the Invention

An important objective of the present invention is to simplify the treatment of dental root canals and to provide a treatment system which enables the dentist to be more confident that remnants of decay and bacterial contamination within the canal have been removed, prior to obturation of the canal to seal it.

Another object is to reduce the time normally required to prepare a root canal for obturation and also preparing the canal for alternative systems of obturating the canal which can be co-ordinated with the preparation of the canal.

According to one aspect of the invention there is provided a method of treating a dental root canal which comprises the steps of:-

(a) gaining access to the root canal;

(b) introducing a flowable photosensitiser into the root canal;

(c) activating the photosensitiser by exposing the walls of the root canal to laser light via an optical fibre within the root canal to kill bacteria within the root canal; and

(d) obturating the root canal.

As mentioned above, the root canal is first opened up and necrotic material removed by filing or reaming. One convenient method of cleaning out the root canal is by using endodontic instruments having a tapered profile. Normally, a series of instruments are used of increasing length and decreasing diameter in order to form a conical shaped canal which tapers downwardly to the apex. These instruments may be used both manually or, conveniently, may be fitted to a conventional rotary dental handpiece. During and after the canal shaping step, debris loosened by the mechanical debriding of the interior and walls of the canal is removed by irrigation and organic debris dissolved. Traditionally, aqueous sodium hypochlorite solution is used, e.g. at a concentration of 2~3%. These are used in copious volumes during the debriding procedure to remove solid debris or kill bacteria (Chow et al, 1983, J. Endodont. 9,475).

In the method of the present invention, sodium hypochlorite may be used for initially cleaning and flushing away loosened debris. However, an aqueous solution of the photosensitiser may alternatively be used in this step, or at least after the initial debris has been removed and the hypochlorite solution flushed away.

The next step is to introduce the photosensitiser dye into the root canal. Preferably, the photosensitiser is a toluidine blue dye which is employed in an aqueous solution, although other photosensitisers may be used as mentioned in EP 0637976. On contact with the bacteria, the dye or other photosensitiser conjugates with the bacteria and once photosensititation has occurred, the site is irradiated with light of a specific wavelength which is strongly absorbed by the photosensitiser. The wavelength of light is specific to the absorption of each photosensitiser. The activation of the dye leads to singlet oxygen release and results in death of the bacteria. It is important that the light is guided closely to areas which may be contaminated with bacteria. This is best done by introducing a light guide or optical fibre into the root canal. In order to ensure that the light is directed onto the walls of the root canal, the fibre tip should be appropriately shaped. The optic fibre may have a spherical or cylindrical surface in the region of the distal end. The production of this type of tip or emitter is described in US Patent No. 5,073,402. In essence, the tip is preferably formed by contacting the distal end of the optic fibre with a light-curable composition, which in its cured state is transparent or translucent, while passing coherent light through the fibre at a wavelength causing curing of the composition. Suitable light-curable compositions include acrylate and methacrylate monomers, including epoxy and urethane acrylates and methacrylates. Such compositions may

contain photochemical initiators and free radical generating additives such as α-diketones (camphoroquinone), benzoyl peroxides and dimethyl-p-toluidine. It may also be desirable to include a minor amount of a dispersed pigment in the tip, e.g. up to about 1~2% by weight of a white pigment, such as TiO_2. This has a scattering effect of the light transmitted by the fibre and ensures that the walls of the canal are uniformly illuminated. A generally isotropic tip can be formed by immersing the optic fibre tip in a bath of a light-curable composition, e.g. as described in US Patent No. 5,073,402. The shape of the tip may be predetermined, e.g. a cylindrical tip may be formed by introducing the fibre tip into a tube containing the polymerisable composition. By selecting a polytetrafluoroethylene (PTFE) or silicone tube, it can be readily stripped away after the light-curable resin has been polymerised. A spherical tip can be produced by the technique described in the above US Patent.

After the root canal has been treated with the photosensitiser and irradiated with light, the root canal is dried, e.g. by aspiration and using absorbent points. The canal is then obturated using a suitable system to seal the canal. This may involve the use of conventional sealing system such as shaped gutta percha, silver or titanium points cemented with an endodontic sealer. Examples of these include zinc oxide/ eugenol and calcium hydroxide based cements and also epoxy resins. Conventional obturation systems may be used such as those employing gutta percha are generally convenient. One suitable system involves introducing gutta percha in heated, softened form on a rod-like carrier into the canal. This procedure is described in European Patent Application No. 0337024. A similar procedure is described in US Patent No. 5149268.

Alternatively, the canal is obturated with a light-curable filling composition. The light curable composition may be cured by irradiation by light of a wavelength specific to activate the in situ system, introduced through an optical fibre positioned within the root canal. The optical fibre is generally provided with a distal tip for spreading the light substantially uniformly, and may be the same optical fibre that is used to guide light into the canal to activate the photosensitiser. However, it may be necessary to use light of a different wavelength for curing the sealant than for activating the photosensitiser. After the filling material has been cured, the optical fibre may remain entombed in the root canal as part of the obturation.

The invention also includes a kit of parts for treating a dental root canal which comprises:-

(a) a flowable photosensitiser;

(b) an optical fibre having a distal portion for emitting light and adapted for introduction into a root canal so that the tip is capable of reaching the apical region of the root canal, said optical fibre being connectable proximally with a means for generating light; and

(c) obturating means for sealing the canal.

In one form of the invention, the obturating means is a flowable, light curable filling composition.

It will be appreciated therefore that in one aspect the invention makes use of a combination of a photosensitive substance and a light source operating at the appropriate wavelength to activate the photosensitiser. A further aspect of the invention is the delivery mechanism, which permits the delivery of the photosensitiser

either at or near the apex of the root canal to ensure that the photosensitiser will contact the debris and bacteria. A related aspect of the invention is the provision of a specially shaped spherical or cylindrical tip to an optical fibre which permits application of light of appropriate wavelength to the region of the apex of a tooth. A still further aspect is the provision of a specially shaped optical tip to provide uniform light near the apex of the tooth. A further element is the provision of a novel sealing or filling material, which will prevent re-infection of the canal from either the access cavity or via the apical foramen. The sealing or filling material may be delivered via the novel delivery system.

As mentioned above, the pulp chamber and coronal region of the root canal is accessed in the normal way using a high speed dental drill. Alternatively, a laser may be used to expose the pulpal chamber and the entrance to the root canal. After initial estimation of canal length which may be carried out by radiography or use of electro optical detection devices, the canal opening may be increased by reaming the canal. The canal may then be irrigated with a known irrigant such as with aqueous hypochlorite or more preferably with the photosensitiser. This may be achieved using a fine tipped syringe or, alternatively, with a specialised dispensing accessory as described below. Turbulent flow may be induced when injecting the photosensitiser into the canal as described in Gooden, 1976, 2: 2571, Chow J. Endodont 1983 9.47. Effective irrigation is achieved by preparing an inwardly tapered canal to ensure the irrigants reach to the apex. This may be facilitated by the use of appropriate instruments.

After introducing the photosensitising agent into the root canal in the tooth, the agent is activated using light delivered by an optical fibre from the specific light source. The wavelength employed depends on the absorption spectra of the photosensitiser. Toluidine blue O is preferably employed as the photosensitiser and has an absorption maximum in the range of 630~660 nm. Semiconductor lasers, gallium/arsenide and helium/neon lasers may be used. The laser light may be continuous or pulsed. It has been found to be important to spread the laser light within the canal rather than focus it on a small target area. One way of achieving this is to provide an optical fibre which terminates in a tip of specific shape; this may be an isotropic tip of spherical configuration.

Another method is to provide a distal portion having curved surfaces, such as cylindrical surfaces. The light-spreading portion may be larger than the diameter of the optical fibre or substantially the same size. The light spreading portion may be formed by removing the internally reflecting outer layer of the optical fibre over a portion of the probe or by providing an extended portion of the desired shape having no internal reflecting portion. Alternatively, the internal light reflecting coating may be omitted in the desired area when forming the coating. One method of forming such a tip is described in US Patent No. 5,073,402.

Essentially, the light-spreading distal tip may be conveniently formed by moulding or casting a curable light transmissive composition on the end of the optical fibre. A spherical tip may be formed by dipping the optical fibre into a polymerisable composition and curing the adherent droplet, while supporting the droplet in a non-miscible liquid. Curing may be effected by passing light of the appropriate

wavelengths for curing along the optical fibre. Suitable polymerisable compositions include light curable acrylate and methacrylate compositions, including those described below as suitable sealant materials. It may be desirable to include a light-scattering material, such as a dispersed pigment, within the polymerisable material to increase the uniformity of irradiation of the root canal. However, the cured tip will be transparent or translucent to light of the wavelength selected for sensitising the dye.

Other shaped tips may be formed by moulding or casting the desired shape onto the end of the optical fibre.

The Photosensitiser

The photosensitiser or dye is used for the disinfection of the internal surface of the root canal by placing a liquid or gel containing the photosensitiser in contact with the debris and bacteria. The interior of the root canal is then irradiated with light of an appropriate wavelength that will be absorbed by the photosensitiser.

In preferred aspects of the invention, the photosensitiser and laser combination may be applied to:-

(a) disinfection or sterilisation of the root canal after initial access has been gained to the root canal of the infected tooth; or as an adjunct to conventional preparation prior to obturate of the canal;

(b) destruction of carious microbes on the internal root surface in order to prevent reinfection.

Photosensitising agents used in this invention are generally non toxic to the target microbes in the concentrations envisaged or to the surrounding tissue.

However, there is no requirement that the photosensitiser should not be toxic to the microbes. Since the exposure times are short, it may be acceptable to use compounds which have some slight toxicity to the tissue.

It is preferred that the photosensitisers used will be capable of absorption in the red end of the visible spectrum or at longer wavelength, as these wavelengths will have greater penetrating powers in the dental tissue surrounding the canal.

The preferred photosensitisers are those effective against Gram Negative bacteria associated with endodontic lesions. Common types of bacteria found in root canal infections contain facultative anaerobes and strict anaerobes and are described in Lewes MAO, McFarlane TW and McGowan DAJ Medical Microbiology 21:101:1986. These include:-

Facultative Anaerobes including Streptococcus milleri and Actinomyces naeslundi. Strict Anaerobes including Bacteroides gingivalis, Bacteroides melaninigenicus, Bacteroides oralis, Peptococcus species and Peptostreptoccus species. The classification of these bacteroides type bacteria include Porphyromonas [gingivalis and endodontalis] and Prevotella [melaninogenica and intermedia]. The presence of these bacteria in an infected root canal or after inadequate cleaning will lead to infection and pain and discomfort. The function of the photosensitiser is to bind to the bacteria and to release singlet oxygen on interacting with the laser light. Of the available photosensitisers, the currently preferred is Toluidine blue O. Alternatively, aluminium disulphonated phthalocyanine chloride, methylene blue or azure blue chloride may be used. While the dye may be non specific, it can be made specific to the microbes within the root canal.

The Laser

The concentration of photoinitiator and laser power are matched to provide maximum penetration of tissue and kill rates.

The concentrations of dye range from 0.00001% to 2%. The currently preferred concentration is 0.0001 to 0.2%, especially 0.001 to 0.1%.

The preferred laser irradiation time of the photosensitiser is between 10 seconds and two minutes and the preferred exposure time is between 30 seconds and 90 seconds.

The laser power is preferably between 25 and 80 mW, the most preferred being about 60 mW. The laser power/exposure time combination may be varied to give a desired dose.

The photosensitiser solution concentration may be influenced by any extrinsic fluid and concentration may be increased to compensate for this.

In order to modify the surface of hard tissue and to enable the photosensitising agents to have maximum effect, potentiating agents may be used as adjuncts to the photosensitising solution. These may be used in conjunction with, prior to or subsequent to the photosensitising solution. These adjuncts include:-

- Acids to produce a solution pH of 4.5 or above
- Acids to penetrate and remove organic/inorganic debris
- Wetting agents such as HEMA (hydroxyethyl methacrylate) and glutaraldehyde
- Demineralising agents such as chelating agents of the type EDTA disodium.

Such materials may be citric acid, polyalkenoic and polyphosphonic acid, phosphoric acid, EDTA and HEMA or other such acids as are known for use in this technique. EDTA and citric acid have an adverse effect on the bacterial kill rate if used simultaneously with the photosensitiser. Thus, in the case of these adjuncts, they should be employed prior to or after treatment with the photosensitiser and the treated area flushed with a wash liquid prior to treatment with the photosensitiser. Phosphoric acid, particularly when buffered to a pH of 4.5 or above appears to have a beneficial effect on bacterial kill rates when used at the same time as the photosensitisation treatment.

A further addition to the photosensitising phase is the addition of remineralising solution to be applied with or subsequent to the application of the dye.

Suitable agents are described by Causton BE and Newell Johnson NW, 1982, BDJ:152, 9-11, Levine RS, Beech DR and Garton B, 1977, BDJ, 143, 275-277 or Pearse and Nelson Caries Research, 1988 22, 362-370.

These may be used prior to and/or subsequent to application of the photosensitiser.

It is important that these agents do not interfere with the photosensitising process, in particular the use of free radical and singlet oxygen scavenging materials should be avoided.

The photosensitiser may be delivered by a syringe or by a unit dose delivery device, which may include a thin flexible tube which may be perforated along the final part of its distal end, e.g. the last 15 mm of its length. The perforated tube, whose diameter is preferably a maximum of 0.1 mm, will be inserted up the canal

without binding against the walls. This will normally be within the apical third of the canal (this being the third of the root canal closest to the root apex), and as close to the apex as achievable without binding on the walls. The dye is then injected, e.g. via a unit dose cartridge, through the tube permitting the dye to coat the whole length of the walls of the root canal. The unit dose syringe and tube will then be removed and the fibre connected to a suitable light source and inserted into the canal. The photosensitiser dye will be activated by the light source.

The filling or sealing material

A further aspect of the invention is that a fluid sealing agent may be syringed up through the delivery system previously described in connection with the photosensitiser. This will coat the walls of the root canal and displace air from the canal as it fills the canal through a tube or syringe tip terminating in the region of the apex. The sealing agent may then be cured using a visible light source, via an optical fibre tipped with an isotropic tip.

These may be resins such as those described as dental adhesives in Patent Application Nos. PCT/GB92/02128; PCT/GB98/00072; US 5,172,763 and US 5,063,257, and other curable resin systems which are employed as dental adhesive and filling materials, e.g. those described in the following patents and applications:]

EP 0356868	WO 97/00065
GB 2107341	UK 1488403
US 5520725	US 4627097
US 1428165	US 4001483

The hermetic seal after bacterial killing is an integral part of the endodontic treatment technique since it is by these means that the bacterial re-infection is minimised. This may be achieved using existing dental materials.

The preferred materials may have a viscosity which may be varied to suit the application. Preferred viscosities are from 0.33 to 1340 centipoise. Where it is used as a dentine substitute, the viscosity is similar to that of water and has mechanical properties such as flexural strength after polymerisation in the range 80 to 170 Mpa. Shrinkage during polymerisation will be in the range of 0.5 to 4.5% by volume. The dentine substitute is made of a blend of resins, which will provide a range of viscosities to suit the intended application.

These may be di-methacrylates or methacrylates as set out in the patents mentioned above. The preferred resin system is a mixture of urethane dimethacrylate (UDMA), bisphenol-A-glycidyl dimethacrylate (BisGMA) and tetrahydrofurfuryl methacrylate (THFMA), which contains THFMA in the range of 30~90% by weight of THFMA. These may be in various proportions, the preferred composition being THFMA 50%, UDMA 33% and BisGMA 17%.

The material may be polymerised chemically or by application of light of a particular wavelength. Sealant materials based on light curable acrylates or methacrylates are commonly cured with light having a wavelength of about 450-470nm.

Cold cure initiator systems which do not require the addition of external energy (heat or light) are materials such as benzoyl peroxide as an initiator and N,N-dimethyl-p-toluidine as an activator.

Preferred light activation systems are those including camphorquinone and an amine. Other activation systems may also be used.

The initiators should be present in an appropriate amount to provide an adequate level of conversion and adequate rate of conversion. They are usually present in amounts between 0.1% and 12% of the weight of the monomer mixture. Preferred values are between 0.5 and 5% by weight of the monomer mixture.

Various additives may optionally be included in the mixture such as antioxidants, stabilisers using UV inhibitors and polymerisation inhibitors, pigments and therapeutic agents such as antibiotics, corticosteroids and other medicinal agents such as metal ions.

Alternative materials such as sol-gel glasses may also be used as the sealing agents delivered in a similar manner to that described above.

The most preferred obturating materials comprise those which seal the canal by deformation under pressure. The root canal sealer which acts as a sealing agent between the canal wall and the obturating material is gutta percha. Its properties allow it to be compressed against the canal wall. The gutta percha points are matched in size to the shaped canal. The gutta percha can be laterally condensed, vertically condensed, heat or cold compacted. A range of additional techniques may be used including heat softening and adapting. Injection of warm gutta percha may also be used. The technique recommended by Tulsa Dental Co. under the name "Thermafil" might also be used to obturate the canal. Here the gutta percha is formed around a plastic pin. The gutta percha is heated and the pin and gutta percha

inserted into the root canal. Pressure is applied with the plastic pin forcing the softened material into all the orifices in the canal walls.

A major advantage of the present invention is that the technique of applying laser light to the photosensitiser within the canal gives a much higher level of assurance to the dentist that residual infection has been eradicated. In part, this is because the photosensitiser is absorbed into the side passages leading from the main canal and that the laser light passes through a significant thickness of dentine.

The accompanying drawings illustrate the manner in which the invention may be carried into effect.

Figure 1 is a schematic longitudinal cross-section through a tooth with one form of optical fibre and tip in place in a root canal;

Figure 2 is a enlarged sectional view of the optical fibre;

Figure 2a is a schematic view of a dental handpiece fitted with an optical fibre and tip and a tube for introducing photosensitiser into a root canal;

Figure 3 is a section through a single dose device for delivering a photosensitiser solution into the root canal;

Figure 4 is a perspective view of a laser housing connected to a dental handpiece;

Figure 5 is a view in the direction of the arrow "X" in Figure 4; and

Figure 6 is a graph showing the effect of increasing the light transmission of carious dentine by demineralisation with EDTA.

The tooth (1) is first drilled to access the entrance (2) to the infected root canal (3), and the canal opened up and debrided using conventional instruments. Loose

debris is suctioned away and, optionally, the canal is flushed with a hypochlorite solution and then with water. A photosensitiser solution, e.g. Toluidine blue O, in dilute aqueous solution (concentration about 50μg/ml) is then introduced into the root canal using a fine-tipped syringe having an obliquely angled tip, or a disposable dispenser such as shown in Figures 2a or 3. Referring to Figure 3, the dispenser comprises a thin-walled cannula (10) having a reservoir (11) for photosensitiser solution attached to its proximal end. The connection between the reservoir and the cannula is sealed with a frangible membrane 12. At its distal end, the cannula is perforated with small holes (13) which permit the escape of liquid from the cannula. In use, the cannula is inserted into the root canal until the distal end is close to the apex of the canal. Photosensitiser is discharged into the root canal by pressing on the reservoir (11), thus causing the membrane to rupture and liquid to flow out of the distal end and through the perforations (13). The perforations (13) ensure that the walls of the root canal are wetted with photosensitiser solution. Preferably, the photosensitiser is allowed to remain in contact with the root canal to permit the photosensitiser to be absorbed by bacteria within the canal, normally about 20 to 40 seconds. The dispenser is then removed and an optical fibre (20), as shown in Figure 2, is introduced into the root canal (3) and laser light having a wavelength of about 630/640 nm guided into the canal.

As can be seen best in Figure 2, the optical fibre is formed with a transparent distal spherical portion (21), typically of about 800 microns diameter. This has the effect of diffusing light passed down the fibre and ensures that light emerging at the

tip (21) is scattered uniformly around and in upward and downward directions in the root canal.

It may be desirable to move the tip of the optical fibre relatively to the canal, either stepwise or continuously, while irradiating the interior of the canal. For example, the tip may be inserted initially to the apex of the canal and then gradually withdrawn, while irradiating the canal. This may be facilitated by the fibre carrying incremental markings on its external surface similar to the tip dimensions. The operator may withdraw the tip incrementally, using the marks to ensure that irradiation of the photosensitiser is carried out over the whole canal length. Instead of an optical fibre having a spherical tip, a fibre having a generally cylindrical distal part may be used. For example, the tip may comprise a 3mm long cylindrical tip having a diameter of about 200 microns. This has approximately the same area as the spherical tip referred to above.

Figure 2(a) shows a developed form of the system shown in Figures 1, 2 and 3. The handpiece (42) has a "plug in" optic fibre (4) having an isotropic tip (5). The fibre is received as a snap-fit in the handpiece (42) and is optically connected through the handpiece to a laser source in the console (41). Surrounding the optic fibre is a hollow tube (6). Contained within the handpiece are reservoirs (7) and (8) filled, respectively, with photosensitiser dye and sealant composition. Feed tubes (9) and (10) connect the reservoirs to the tube (6). The reservoirs may be squeezable pouches so that on applying pressure to the respective pouch, dye or fluid resin can be injected as required into the tube (6) and thence into the prepared canal (2) in the tooth. Preferably, the reservoirs, fibre tip and tube are disposable.

A more developed version of the laser console and a dental handpiece carrying the optical fibre is shown in Figures 4 and 5. Figure 4 shows a perspective view of the laser housing (41) linked to a dental handpiece (42). An optical fibre (43) is held in the part of the handpiece which will be introduced into the patient's mouth. The optical fibre (43) is a disposable "plug in" element which carries an isotropic tip as described above. Housing (41) contains laser generating equipment whose output is connected to a flexible heavy duty optical fibre within the handpiece, the output from the fibre (44) is connected to the disposable fibre (43). Two laser sources may be accommodated in the housing (41), one capable of emitting laser light at a wavelength of about 670 nm for effecting the photosensitising treatment, and the other capable of emitting laser light for curing the resin sealant. Light guides and a beam splitter may be provided so that light from each laser source can be selectively switched to the tip (43). The fibre tip may be changed after the photosensitising treatment has been carried out and fresh tip plugged into the handpiece in order to carry out curing of the resin sealant.

Figure 5 shows a control panel (45) having a touch screen (46) for programming the laser power and duration of treatment. For convenience, the apparatus can be made in portable form and incorporate a rechargeable battery.

After the photosensitiser has been irradiated with laser light for a sufficient period to ensure sterilisation of the interior of the canal (usually 30 seconds to 1 minute at a laser power of between 40 - 80 mW), the optical fibre is removed.

It may be desirable at this point to aspirate photosensitiser from the canal.

A fluid sealing or filling composition is then introduced into the canal. For this purpose, a unit dose dispenser such as that shown in Figure 2a may be used. An optical fibre such as shown in Figure 2a may then be introduced into the root canal and light passed down the fibre to cure the sealant material. This will hermetically seal the root canal from reinfection. The sealant material may incorporate a radio-opaque filler material, such as a barium or strontium salt, e.g. the fluoride. It may further contain amine fluoride. The projecting part of the optical fibre may then be cut off and the access hole may be filled with a conventional dental filling material such as an amalgam or glass ionomer resin.

Experiments with slices of dentine cut from extracted human teeth have shown that it is desirable to pretreat a canal with a demineralisation solution, e.g. of EDTA prior to the photosensitisation treatment. Even a short pre-treatment with EDTA, e.g. as a 0.1 molar aqueous solution, substantially increases the distance through which the laser light can pass. Even pre-treatment of the dentine with 0.1 molar EDTA or other demineralisation solution for as little as 15 seconds increased the depth of light transmission and dye penetration significantly. This is an important finding and enables the dentist to be confident that bacteria has been killed in passages leading from the canal in the treated tooth. The effect of demineralisation treatment on the light transmission and dye absorption is shown graphically in Figure 5. The effect of the demineralisation additive appears to be self-limiting in that the maximum demineralised area extends essentially only to the boundary of the dentine affected by a carious lesion.

Alternatively, the sterilised canal may be sealed by means of gutta percha plugs supported on a plastic or metal rod-like carrier as described in EPA 0337024 or USA 5149268.

CLAIMS:-

1. A method of treating a dental root canal which comprises the steps of:-

(a) gaining access to the root canal;

(b) introducing a flowable photosensitiser into the root canal;

(c) activating the photosensitiser by exposing the walls of the root canal to light via an optical fibre within the root canal to kill bacteria within the root canal and pulp chamber; and

(d) obturating the root canal.

2. A method according to claim 1 wherein the root canal is obturated with gutta percha, silver or titanium points.

3. A method according to claim 2 in which the root canal is obturated with an obturation device comprising gutta percha carried on a rod-like carrier, the device being shaped and dimensioned so that on forcing it into the canal, the gutta percha is deformed and fills the canal.

4. A method according to claim 1 in which the root canal is obturated with a curable filling material.

5. A method according to claim 4 wherein the curable filling material is cured by irradiation with light through an optical fibre within the root canal.

6. A method according to claim 5 wherein the same optical fibre is used for activating the photosensitiser and the curable filler material.

7. A method according to any one of the preceding claims wherein the optical fibre has a substantially isotropic tip.

8. A method according to any one of the preceding claims in which the optical fibre has a spherical or cylindrical portion at or close to the distal end to spread radiation around and along the canal.

9. A kit of parts for treating a dental root canal which comprises:-

(a) a flowable photosensitiser;

(b) an optical fibre having a portion at or close to the distal end which is shaped to spread radiation around and along the canal, said fibre being adapted for introduction into a root canal so that the tip is capable of reaching the apical third of the root canal, said optical fibre being connectable proximally with means for generating laser light; and

(c) obturating means for sealing the canal.

10. A kit according to claim 9 wherein the flowable sensitiser comprises a dilute aqueous solution of toluidine blue.

11. A kit according to claim 9 wherein the obturating means comprises a preformed plug of gutta percha or silver or titanium points.

12. A kit according to any one of the preceding claims wherein the flowable sensitiser is contained in a cartridge which includes a delivery tube for introducing the photosensitiser into the canal.

13. A kit according to claim 9 wherein the obturating means comprises a flowable, curable sealing composition.

14. A kit according to any one of claims 8 to 13 wherein the distal portion of the optical fibre comprises a translucent polymer composition containing a minor

amount of a dispersed pigment sufficient to cause light transmitted by the fibre to be scattered around the canal.

15. A kit according to any one of claims 8 to 14 wherein the distal portion of the optical fibre is formed by polymerising a light-curable polymerisable composition on an end of the optical fibre.

16. Use in the manufacture of materials for sterilising and sealing a dental root canal of a kit of parts comprising:

(a) a flowable photosensitiser;

(b) an optical fibre which is shaped and dimensioned to pass into a root canal to the region of the apex thereof, said optical fibre being connectable proximally with means for generating laser light at a wavelength which is capable of being absorbed by the photosensitiser and said optical fibre having a distal portion which is shaped to spread the laser light around and along the canal; and

(c) obturating means for sealing the canal.

17. Use according to claim 16 in which the photosensitiser is an aqueous dye.

18. Use according to claim 17 in which the photosensitiser is toluidine blue in aqueous solution.

19. Use according to any one of claims 16 to 18 in which the obturating means comprises gutta percha supported on a rod-like support.

20. Use according to any one of claims 16 to 18 in which the obturating means comprises a light curable resin composition.

21. Use according to any one of claims 16 to 20 wherein the distal portion of the optical fibre comprises a translucent polymer composition containing a minor amount of a dispersed pigment sufficient to cause light transmitted by the fibre to be scattered around the canal.

CLAIMS:-

1. A method of treating a dental root canal which comprises the steps of:-

(a) gaining access to the root canal;

(b) introducing a flowable photosensitiser into the root canal;

(c) activating the photosensitiser by exposing the walls of the root canal to light via an optical fibre within the root canal to kill bacteria within the root canal and pulp chamber; and

(d) obturating the root canal.

2. A method according to claim 1 wherein the root canal is obturated with gutta percha, silver or titanium points.

3. A method according to claim 2 in which the root canal is obturated with an obturation device comprising gutta percha carried on a rod-like carrier, the device being shaped and dimensioned so that on forcing it into the canal, the gutta percha is deformed and fills the canal.

4. A method according to claim 1 in which the root canal is obturated with a curable filling material.

5. A method according to claim 4 wherein the curable filling material is cured by irradiation with light through an optical fibre within the root canal.

6. A method according to claim 5 wherein the same optical fibre is used for activating the photosensitiser and the curable filler material.

7. A method according to any one of the preceding claims wherein the optical fibre has a substantially isotropic tip.

8. A method according to any one of the preceding claims in which the optical fibre has a spherical or cylindrical portion at or close to the distal end to spread radiation around and along the canal.

9. A kit of parts for use in sterilising and sealing a dental root canal (2), said kit of parts comprising:-

(a) a flowable photosensitiser which is absorbed by bacteria;

(b) an optical fibre (4,20) having a portion (5,21) at or close to the distal end which is shaped to spread radiation around and along the canal, said fibre being adapted for introduction into a root canal so that the tip is capable of reaching the apical third of the root canal, said optical fibre being connectable proximally with means (41) for generating laser light capable of being absorbed by the photosensitiser; and

(c) obturating means for sealing the canal.

10. A kit according to claim 9 wherein the flowable sensitiser comprises a dilute aqueous solution of toluidine blue.

11. A kit according to claim 9 wherein the obturating means comprises a preformed plug of gutta percha or silver or titanium points.

12. A kit according to any one of claims 9 to 11 wherein the flowable sensitiser is contained in a cartridge (7,11) which includes a delivery tube (9,10) for introducing the photosensitiser into the canal.

13. A kit according to claim 9 wherein the obturating means comprises a flowable, curable sealing composition.

14. A kit according to any one of claims 8 to 13 wherein the distal portion of the optical fibre comprises a translucent polymer composition containing a minor amount of a dispersed pigment sufficient to cause light transmitted by the fibre to be scattered around the canal.

15. A kit according to any one of claims 8 to 14 wherein the distal portion of the optical fibre is formed by polymerising a light-curable polymerisable composition on an end of the optical fibre.

16. A kit according to any one of claims 8 to 15 wherein the optical fibre (4,20) has a substantially isotropic tip (5,21) so that it is capable of irradiating the interior of the canal in an arc of up to 360°.

17. Use in the manufacture of materials for sterilising and sealing a dental root canal (2) of a kit of parts comprising:

(a) a flowable photosensitiser which is absorbed by bacteria;

(b) an optical fibre (4,20) which is shaped and dimensioned to pass into a root canal to the region of the apex thereof, said optical fibre being connectable proximally with means for generating laser light at a wavelength which is capable of being absorbed by the photosensitiser and said optical fibre having a distal portion (5,21)which is shaped to spread the laser light around and along the canal; and

(c) obturating means for sealing the canal.

18. Use according to claim 17 in which the photosensitiser is an aqueous dye.

19. Use according to claim 18 in which the photosensitiser is toluidine blue in aqueous solution.

20. Use according to any one of claims 17 to 19 in which the obturating means comprises gutta percha supported on a rod-like support.

21. Use according to any one of claims 17 to 19 in which the obturating means comprises a light curable resin composition.

22. Use according to any one of claims 17 to 21 wherein the distal portion of the optical fibre comprises a translucent polymer composition containing a minor amount of a dispersed pigment sufficient to cause light transmitted by the fibre to be scattered around the canal.

23. Use, in the manufacturing of a kit of parts for use in sterilising and sealing a dental root canal (2), the kit of parts comprising:-

(a) a flowable photosensitiser comprising a photosensitive dye;

(b) an optical fibre (4,20) which is connectable proximally to means for generating laser light at a wavelength capable of being absorbed by the photosensitiser and which has a substantially isotropic distal tip (5,21) which is free from an internally reflecting layer, the tip (5) being shaped and dimensioned so that it can be moved along the canal to activate the photosensitiser; and

(c) obturating means for sealing the canal comprising a preformed plug of gutta percha or silver or titanium points or a flowable, photo-curable sealing composition.